

SPECIALTY LABORATORIES INC

Form 10-Q

November 09, 2004

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

ý **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES
EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2004

OR

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES
EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission file number 001-16217

SPECIALTY LABORATORIES, INC.

(Exact Name of Registrant as Specified in Its Charter)

California

(State or Other Jurisdiction of Incorporation or Organization)

95-2961036

(IRS Employer Identification No.)

2211 Michigan Avenue

Santa Monica, California 90404

(Address of principal executive offices, including zip code)

Registrant's Telephone Number, Including Area Code: **(310) 828-6543**

Not Applicable

(Former name, former address and former fiscal year, if changed since last report)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

As of November 1, 2004, there were approximately 22,936,028 shares of Common Stock outstanding, no par value.

SPECIALTY LABORATORIES, INC.

FORM 10-Q QUARTERLY REPORT

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CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q, (the Quarterly Report) including the information incorporated herein by reference contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These statements relate to expectations concerning matters that are not historical facts. Words such as projects, believes, anticipates, will, estimate, plans, expects, intends, and similar words and expressions are intended to identify forward-looking statements. These forward-looking statements are based on the current expectations, assumptions, estimates and projections about Specialty Laboratories, Inc. and the clinical laboratory industry. Although we believe that such forward-looking statements are reasonable, we cannot assure you that such expectations will prove to be correct. We undertake no obligation to revise or publicly update any forward-looking statement for any reason. All forward-looking statements attributable to Specialty Laboratories, Inc. are expressly qualified in their entirety by the cautionary statements of this Quarterly Report and by the discussion of Risk Factors included elsewhere in this Quarterly Report, and in other filings with the Securities and Exchange Commission (SEC) made from time to time by Specialty Laboratories, Inc., including our periodic filings on Form 10-K, Form 10-Q and Form 8-K. If any of these risks actually occur, our business, financial condition, results of operations and future growth prospects could be materially adversely affected. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial also may impair our business. Any adverse effect on our business, financial condition or results of operations could result in a decline in the trading price of our common stock and the loss of all or part of your investment.

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Specialty Laboratories, Inc.

Consolidated Balance Sheets

(Dollar amounts in thousands)

| | December 31, 2003 | September 30, 2004 (Unaudited) |
|---|-------------------|-----------------------------------|
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 27,563 | \$ 23,709 |
| Short-term investments | 9,104 | 4,008 |
| Accounts receivable, less allowance for doubtful accounts of \$2,720 as of December 31, 2003 and \$2,927 as of September 30, 2004 | 22,239 | 25,735 |
| Receivable from sale of property | | 3,500 |
| Refundable income taxes | 126 | 630 |
| Deferred income taxes | 1,155 | 1,155 |
| Inventory | 2,729 | 2,895 |
| Prepaid expenses and other assets | 2,680 | 2,596 |
| Total current assets | 65,596 | 64,228 |
| Property and equipment, net | 61,535 | 32,800 |
| Long-term investments | | 15,902 |
| Deferred income taxes | 5,029 | 5,029 |
| Goodwill, net | 5,655 | 5,655 |
| Other assets | 4,738 | 5,859 |
| | \$ 142,553 | \$ 129,473 |
| Liabilities and shareholders equity | | |
| Current liabilities: | | |
| Accounts payable | \$ 8,834 | \$ 6,915 |
| Accrued liabilities | 6,261 | 4,534 |
| Total current liabilities | 15,095 | 11,449 |
| Long-term debt | 5,019 | |
| Other long-term liabilities | 1,939 | 1,510 |
| Shareholders equity: | | |
| Preferred stock, no par value: | | |
| Authorized shares 10,000,000 | | |
| Issued and outstanding shares none | | |
| Common stock, no par value: | | |
| Authorized shares 100,000,000 | | |
| Issued and outstanding shares 22,570,256 as of December 31, 2003 and 22,882,025 as of September 30, 2004 | 103,005 | 104,303 |
| Retained earnings | 17,436 | 12,345 |
| Deferred stock-based compensation | (13) | |
| Accumulated other comprehensive income (loss) | 72 | (134) |
| Total shareholders equity | 120,500 | 116,514 |
| | \$ 142,553 | \$ 129,473 |

See accompanying notes.

Specialty Laboratories, Inc.

Consolidated Statements of Operations

(Unaudited)

(Dollar amounts in thousands except per share data)

| | Three Months Ended September 30, | | | | Nine Months Ended September 30, | | | |
|---|----------------------------------|---------|------|---------|---------------------------------|---------|------|---------|
| | 2003 | | 2004 | | 2003 | | 2004 | |
| Net revenue | \$ | 29,858 | \$ | 34,632 | \$ | 89,194 | \$ | 99,153 |
| Costs and expenses: | | | | | | | | |
| Costs of services | | 21,342 | | 23,919 | | 64,497 | | 68,775 |
| Selling, general and administrative (exclusive of stock-based compensation charges) | | 11,888 | | 13,505 | | 33,440 | | 36,151 |
| Stock-based compensation charges | | 17 | | 1 | | 52 | | 147 |
| Total costs and expenses | | 33,247 | | 37,425 | | 97,989 | | 105,073 |
| Operating loss | | (3,389) | | (2,793) | | (8,795) | | (5,920) |
| Interest income | | (156) | | (190) | | (549) | | (429) |
| Interest expense | | 11 | | 101 | | 46 | | 101 |
| Loss before income taxes (benefits) | | (3,244) | | (2,704) | | (8,292) | | (5,592) |
| Provision for income taxes (benefits) | | (973) | | (501) | | (2,689) | | (501) |
| Net loss | \$ | (2,271) | \$ | (2,203) | \$ | (5,603) | \$ | (5,091) |
| Basic loss per common share | \$ | (0.10) | \$ | (0.10) | \$ | (0.25) | \$ | (0.22) |
| Diluted loss per common share | \$ | (0.10) | \$ | (0.10) | \$ | (0.25) | \$ | (0.22) |

See accompanying notes.

Specialty Laboratories, Inc.

Consolidated Statements of Cash Flows

(Unaudited)

(Dollar amounts in thousands)

| | Nine Months Ended September 30, | |
|---|--|-------------|
| | 2003 | 2004 |
| Operating activities | | |
| Net loss | \$ (5,603) | \$ (5,091) |
| Adjustments to reconcile net loss to net cash provided by (used in) operating activities: | | |
| Depreciation and amortization | 4,989 | 4,669 |
| Tax benefits related to employee stock options | 1,090 | |
| Loss on disposal of property and equipment | | 117 |
| Deferred income taxes | (3,147) | |
| Stock-based compensation charges | 52 | 147 |
| Changes in assets and liabilities: | | |
| Accounts receivable, net | 920 | (3,496) |
| Inventory, prepaid expenses and other assets | (969) | 190 |
| Accounts payable | 4,142 | (1,919) |
| Accrued liabilities | (2,004) | (1,727) |
| Income taxes refundable/payable | 6,762 | (504) |
| Long-term liabilities | (480) | (429) |
| Net cash provided by (used in) operating activities | 5,752 | (8,043) |
| Investing activities | | |
| Purchases of property and equipment | (10,354) | (22,759) |
| Proceeds from sale of property and equipment | | 43,500 |
| Sale (purchase) of investments, net | 4,070 | (11,012) |
| Net cash (used in) provided by investing activities | (6,284) | 9,729 |
| Financing activities | | |
| Borrowings (repayments) under bank loan, net | 5,000 | (5,019) |
| Increase in deferred financing cost | (206) | (1,685) |
| Proceeds from exercise of stock options | 510 | 831 |
| Sale of common stock to employees | 333 | 333 |
| Net cash provided by (used in) financing activities | 5,637 | (5,540) |
| Net increase (decrease) in cash and cash equivalents | 5,105 | (3,854) |
| Cash and cash equivalents at beginning of period | 22,405 | 27,563 |
| Cash and cash equivalents at end of period | \$ 27,510 | \$ 23,709 |
| Supplemental disclosure of cash flow information: | | |
| Receivable from sale of property | | \$ 3,500 |
| Change in unrealized losses on investments | \$ (220) | \$ (206) |
| Deferred income taxes | 88 | |
| Net change in unrealized losses | \$ (132) | \$ (206) |
| Interest paid | \$ 82 | \$ 200 |

See accompanying notes.

SPECIALTY LABORATORIES, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

September 30, 2004

(Unaudited)

NOTE 1. BASIS OF PRESENTATION

Financial Statement Preparation

The accompanying consolidated financial statements of Specialty Laboratories (the Company) have been prepared, without audit, in accordance with U.S. generally accepted accounting principles for interim financial reporting and the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, the consolidated financial statements do not include all of the information and notes required by U.S. generally accepted accounting principles for complete financial statements. In the opinion of management, such interim financial statements contain all adjustments (consisting of normal recurring items) considered necessary for a fair presentation of our financial position, results of operations and cash flows for the interim periods presented. The results of operations and cash flows for any interim periods are not necessarily indicative of results that may be reported for the full fiscal year.

The accompanying consolidated financial statements should be read in conjunction with the audited consolidated financial statements, and the notes thereto, included in our Annual Report on Form 10-K for the year ended December 31, 2003, as filed with the Securities and Exchange Commission.

NOTE 2. GOODWILL AND INTANGIBLE ASSETS

The Company allocates the excess of the purchase price over the fair value of the net assets acquired to goodwill and identifiable intangible assets. Identifiable intangible assets include customer lists and license agreement fees, which are amortized evenly over periods of 10 and 4.5 years, respectively. Effective January 1, 2002, the Company ceased amortization of goodwill in accordance with the provisions of Statement of Financial Accounting Standards (SFAS) No. 142, *Goodwill and Other Intangible Assets*.

Intangible assets (included in other assets) are as follows:

| | December 31, 2003 | September 30, 2004 |
|---|-------------------------------|--------------------|
| | (dollar amounts in thousands) | |
| Customer list related to the acquisition of BBI Clinical Laboratories, Inc. (BBICL) | \$ 1,932 | \$ 1,932 |
| Other intangible assets | 425 | 425 |

NOTE 2. GOODWILL AND INTANGIBLE ASSETS

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| | | | | |
|-------------------------------|----|-------|----|-------|
| Less accumulated amortization | | (750) | | (967) |
| Total intangible assets, net | \$ | 1,607 | \$ | 1,390 |

The estimated amortization expense for intangible assets will be \$289,000 per year through December 31, 2005, \$225,000 for 2006, \$193,000 per year for 2007 through 2010, and \$32,000 for 2011.

NOTE 3. PROPERTY AND EQUIPMENT

Property and equipment consists of the following:

| | December 31, 2003 | September 30, 2004 |
|--|-------------------------------|--------------------|
| | (dollar amounts in thousands) | |
| Information technology equipment and systems | \$ 36,061 | \$ 36,749 |
| Professional equipment | 14,248 | 15,332 |
| Leasehold improvements | 8,846 | 8,924 |
| Land | 8,701 | 0 |
| Office furniture and equipment | 4,223 | 3,854 |
| | 72,079 | 64,859 |
| Less accumulated depreciation and amortization | (44,380) | (48,447) |
| Construction in progress (See Note 9) | 33,836 | 16,388 |
| Total property and equipment, net | \$ 61,535 | \$ 32,800 |

NOTE 4. LONG TERM DEBT

On September 24, 2003, the Company entered into a \$25 million asset-based credit agreement with CIT Business Credit (CIT), a unit of CIT Group Inc. The credit facility is secured primarily by accounts receivable, with the availability of funds based on the outstanding balance of this asset. The original credit agreement provided the Company with an initial \$15 million line of credit. On August 13, 2004, the Company entered into an amendment to its agreement with CIT whereby CIT agreed to assist the Company in obtaining letters of credit in an aggregate amount of up to \$10.1 million. The aggregate amount of outstanding letters of credit reduces the amount that the Company can borrow against its \$15.0 million line of credit. On September 14, 2004, CIT assisted the Company in obtaining a \$9.0 million irrevocable letter of credit with JPMorgan Chase Bank in satisfaction of a requirement in the Company's lease agreement for its Valencia facility. (Please see Note 6 for further discussion.) The principal amount of borrowings was due three years from the closing date, the date the line of credit matures. Interest is computed and payable monthly. Interest is based on the Chase Bank rate plus one-half percent (0.5%) per annum. On September 24, 2004, the Company paid down the entire \$5.2 million borrowed against the line of credit, including approximately \$185,000 of accrued interest.

NOTE 5. STOCK-BASED COMPENSATION

The Company accounts for stock options under the recognition and measurement principles (the intrinsic-value method) prescribed in Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees*, and related interpretations. Compensation cost for stock options is reflected in net income and is measured as the excess of the market price of the Company's stock at the date of grant over the amount an employee must pay to acquire the stock. Compensation cost for fixed awards subject to vesting is recognized pro rata over the vesting period.

The Company has adopted the disclosure provisions required by SFAS No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure*. Pro forma net income, determined as if the Company had accounted for its employee stock options under the fair-value method of that Statement, follows:

| | Three Months Ended September 30, | | | | Nine Months Ended September 30, | | | |
|---|----------------------------------|---------|------|---------|---------------------------------|---------|------|---------|
| | 2003 | | 2004 | | 2003 | | 2004 | |
| (dollar amounts in thousands except per share data) | | | | | | | | |
| Net loss, as reported | \$ | (2,271) | \$ | (2,203) | \$ | (5,603) | \$ | (5,091) |
| Stock-based employee compensation, net of related tax effects for 2003 (1): | | | | | | | | |
| Determined under the intrinsic-value based method | | 12 | | 1 | | 35 | | 147 |
| Determined under the fair-value based method | | (806) | | (928) | | (2,582) | | (3,144) |
| Net loss, as adjusted | \$ | (3,065) | \$ | (3,130) | \$ | (8,150) | \$ | (8,088) |
| Basic loss per common share: | | | | | | | | |
| As reported | \$ | (.10) | \$ | (.10) | \$ | (.25) | \$ | (.22) |
| Pro forma | \$ | (.14) | \$ | (.14) | \$ | (.37) | \$ | (.36) |
| Diluted loss per common share: | | | | | | | | |
| As reported | \$ | (.10) | \$ | (.10) | \$ | (.25) | \$ | (.22) |
| Pro forma | \$ | (.14) | \$ | (.14) | \$ | (.37) | \$ | (.36) |

(1) Compensation determined under the intrinsic-value and fair value based methods in 2004 has not been tax-effected. (Please see Note 8 for further discussion)

These pro forma amounts may not be representative and may vary in future disclosures since the estimated fair value of stock options would be amortized to expense over the vesting period, and additional options may be granted in future years.

The fair value for these options was estimated at the date of grant using the Black-Scholes option-pricing model with the following assumptions:

| | Three Months Ended September 30, | | Nine Months Ended September 30 | |
|---|-------------------------------------|---------|-----------------------------------|---------|
| | 2003 | 2004 | 2003 | 2004 |
| Risk-free interest rates | 3% | 3.3% | 3% | 3.3% |
| Expected dividend yields | 0% | 0% | 0% | 0% |
| Weighted-average expected life of option | 5 years | 5 years | 5 years | 5 years |
| Expected stock price volatility based upon peer companies | .66 | .61 | .66 | .61 |

For sales of the Company's common stock to employees at a price below market value, the difference between the sales price and the market value was charged to expense as of the date of the sales.

On October 13, 2004, the Financial Accounting Standards Board (FASB) concluded that Statement No. 123R, *Share-Based Payment*, which requires all companies to measure compensation cost for all share-based payments (including employee stock options) at fair value, would be effective for public companies for interim or annual periods beginning after June 15, 2005. SFAS No. 123R will eliminate Specialty's ability to account for share-based compensation using the intrinsic value method permitted under Opinion No. 25. Specialty will utilize the modified prospective method, recognizing compensation cost for share-based awards to employees based on their grant-date fair values from the beginning of the year in which the recognition provisions are first applied as if the fair value-based method had been used to account for all employee awards. Under this transition approach, compensation cost will be recognized for all awards granted, modified or settled after the date of adoption as well as to any awards that were not fully vested as of that date. Any adjustments to recognize share-based liabilities at fair value from the beginning of the year through the date of adoption will be recognized as a cumulative effect of a change in accounting principle. Specialty intends to apply the new rules beginning July 1, 2005.

NOTE 6. COMMITMENTS AND CONTINGENCIES

In January 2003, the Company established a \$680,000 irrevocable letter of credit with the Federal Insurance Company, our workers compensation insurance provider for 2003. The letter of credit was increased to \$1,030,000 effective January 2004. The Company elected to utilize a deductible program for 2003 and 2004 for which Federal Insurance Company required a security deposit in the form of a letter of credit. The Company has accrued an estimate for claim deductibles under its workers' compensation programs.

On September 14, 2004, the Company established a \$9.0 million irrevocable letter of credit with JPMorgan Chase Bank that names Lexington Corporate Properties Trust (Lexington), the Company's landlord for its Valencia facility, as the beneficiary. The Valencia facility lease requires the Company to post a security deposit in the form of a letter of credit in connection with the lease agreement for its Valencia facility.

Specialty Laboratories Asia Pte. Ltd., a Singapore corporation, (SLA), is 60% owned by our wholly-owned subsidiary, Specialty Laboratories International Ltd., a British Virgin Islands corporation (SLIL). SLA was headquartered in Singapore but, in early 1999, SLA ceased all operations and is currently insolvent. A former employee of SLA has obtained a judgment for \$350,000 against SLA and a default judgment of approximately \$1.95 million in a wrongful termination action against SLA filed by him in Singapore. The former employee has filed an action against SLA in San Diego Superior Court to attempt to collect on the Singapore judgment and has obtained a default judgment of approximately \$2.5 million against SLA in California. The former employee served discovery upon us and certain of our directors and officers. Our management believes that any claim against us or our directors and officers in connection with these judgments, if made, would be without merit, and we would vigorously defend any such action.

In December 2003, we were served with an action in which we are named as a defendant, together with certain of our former officers, SLIL, and multiple other parties located in Singapore and India, in a lawsuit brought in the High Court of the Republic of Singapore by Dragon Investment Company (Dragon), one of the shareholders in SLA. Dragon has also brought the lawsuit in the name of SLA as a derivative action. The lawsuit alleges, among other things, that SLA and Dragon suffered damages as a result of the winding up of the affairs of SLA and disposition of its assets. The lawsuit also alleges that certain of the defendants breached certain written agreements to allow Dragon to acquire more shares of SLA, that certain of our former officers conspired to run down and dissipate the assets of SLA, and that they fraudulently concealed their actions from Dragon and the other minority shareholder of SLA. We have provided notice to the applicable insurance carriers. While we believe that we have insurance applicable to the defense of the lawsuits, and continue to work with the relevant insurance carriers on the coverage issue, such carriers have not yet acknowledged coverage of the matter. We also believe that the claims against us, SLIL, and our former officers are without merit, and intend to defend the lawsuits vigorously.

NOTE 7. EARNINGS PER SHARE

Basic earnings (loss) per share are computed by dividing net income (loss) by the weighted average number of common shares outstanding for the respective periods. Diluted earnings (loss) per share, calculated using the treasury stock method, gives effect to the potential dilution that could occur upon the exercise of certain stock options that were outstanding during the respective periods presented. Since the Company reported a net loss for the quarter and nine months ended September 30, 2004, these potentially dilutive common shares were excluded from the diluted loss per share calculation because they were anti-dilutive.

Basic and diluted loss per share for the respective periods are set forth in the table below:

| | Three Months Ended September 30, | | | | Nine Months Ended September 30, | | | |
|--|----------------------------------|---------|------|---------|---------------------------------|---------|------|---------|
| | 2003 | | 2004 | | 2003 | | 2004 | |
| (amounts in thousands except per share data) | | | | | | | | |
| Net loss | \$ | (2,271) | \$ | (2,203) | \$ | (5,603) | \$ | (5,091) |
| Basic loss per common share | \$ | (.10) | \$ | (.10) | \$ | (.25) | \$ | (.22) |
| Diluted loss per common share | \$ | (.10) | \$ | (.10) | \$ | (.25) | \$ | (.22) |
| Basic weighted average shares | | 22,331 | | 22,862 | | 22,188 | | 22,782 |
| Dilutive effect of outstanding stock options | | | | | | | | |
| Diluted weighted average shares | | 22,331 | | 22,862 | | 22,188 | | 22,782 |

NOTE 8. DEFERRED INCOME TAXES

The Company reported \$6,184,000 of net deferred tax assets (current and long-term) in the September 30, 2004 balance sheet, with approximately \$10,772,000 of this amount related to federal and state net operating loss carryforwards (NOL s). In September 2004, we recorded an income tax benefit of \$501,000 related to the successful resolution of federal and state tax audits, which were ongoing since the end of 2003. SFAS No. 109, *Accounting for Income Taxes*, requires that deferred tax assets be reduced by a valuation allowance if it is more likely than not that some portion of the deferred tax assets will not be realized. The Company's valuation allowance totaled approximately \$3.4 million at September 30, 2004. Realization of the NOL s generated through September 30, 2004 is dependent on the Company's ability to generate approximately \$24.2 million of federal and \$28.6 million of state ordinary income in future years. Inability to generate the necessary ordinary income could have a material adverse effect on the Company's results of operations in future years. The federal NOL s begin expiring in 2024 and the state NOL s begin expiring in 2014.

NOTE 9. SALE AND LEASEBACK OF BUILDING

On February 11, 2004, the Company entered into an agreement for the sale and leaseback of its Valencia facility with Lexington Corporate Properties Trust (Lexington), a real estate investment trust. Lexington agreed to purchase the existing facility for \$47.0 million. The closing of the sale was completed on March 18, 2004 and the Company received approximately \$26.2 million in proceeds, net of \$1.6 million of financing related expenses. Receipt of the approximately \$19.2 million balance of proceeds was contingent upon the completion of the construction project and the commencement of lease payments to Lexington. During the third quarter of 2004, the Company substantially completed construction activities, relocated its administrative functions from Santa Monica to its Valencia facility and commenced making lease payments to Lexington on September 1, 2004. On September 15, 2004, the Company received approximately \$15.7 million of the \$19.2 million balance of proceeds. Receipt of the \$3.5 million balance of proceeds is expected during the fourth quarter of 2004, contingent upon the completion of certain deliverables to Lexington, including completion of the construction of the laboratory portion of the new facility. The \$3.5 million balance of proceeds has been recorded as a receivable in the Company's balance sheet as of September 30, 2004.

For the first five years, lease payments will be fixed at an annual rate of approximately \$3.5 million and will be adjusted every five years. Lease payments for years 6 through 10 will be the amount necessary to fully amortize the total project cost over 15 years at an interest rate equal to the sum of the then interpolated 15-year U.S. Treasury Bond rate plus 75 basis points. Payments will be increased 10% for years 11 through 15 with an additional 10% increase scheduled for years 16 through 20. The primary term for the lease is twenty years. There are three options to extend the term of the lease: two renewal options of five years each and a third renewal option for four years and six months.

Based on an interpolated 15-year Treasury Rate of 4.33% at August 31, 2004, the estimated minimum lease payments under the terms of the related lease agreement are reflected in the table below. Actual lease payments for years 6 through 20 will be determined at least sixty days prior to the first day of the sixth lease year. These estimates of minimum lease payments are subject to future changes in the interpolated 15-year Treasury Rate, which has increased slightly since the sale and leaseback transaction was completed, and which can be expected to vary further prior to and during years 6 through 20 of the lease.

| | Total | 2004 | Payments due by Period | | 2009 and Beyond |
|-----------------------------|-----------|----------|------------------------|-------------|-----------------|
| | | | 2005 - 2006 | 2007 - 2008 | |
| (amounts in thousands) | | | | | |
| Operating lease obligations | \$ 91,716 | \$ 1,188 | \$ 7,125 | \$ 7,125 | \$ 76,278 |

The lease payments are being accounted for under FASB Technical Bulletin 85-3, *Accounting for Operating Leases with Scheduled Rent Increases*, which requires minimum lease payments with scheduled rent increases to be accounted for on a straight-line basis over the lease term. Rent expense for the facility will be approximately \$4.6 million per year.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL

CONDITION AND RESULTS OF OPERATIONS

The following discussion of our financial condition and results of operations should be read in conjunction with the consolidated financial statements and related notes included elsewhere in this Quarterly Report and the audited consolidated financial statements, and the notes thereto, included in our Annual Report on Form 10-K for the year ended December 31, 2003, as filed with the Securities and Exchange Commission. This section includes forward-looking information that involves risks and uncertainties. See Cautionary Statement Regarding Forward-Looking Statements . Our actual results could differ materially from those anticipated by forward-looking statements due to factors discussed under Risk Factors , Business and elsewhere in this Quarterly Report.

Overview

Specialty Laboratories is a leading hospital-focused clinical laboratory, performing highly advanced, clinically useful testing services for hospitals, laboratories and physician specialist communities nationwide. We believe we offer one of the most comprehensive menu of specialized assays in the industry, with a test menu comprising thousands of different assays. Specialized assays are used to diagnose, evaluate and monitor patients and offer important clinical value. Because of their complexity, these assays are often performed by highly skilled personnel on technologically sophisticated instruments and are therefore offered by a limited number of clinical laboratories.

Our primary clients are hospitals, independent clinical laboratories and physicians. We have aligned our interests with those of hospitals by not competing in the routine test market that provides them with a valuable source of revenue. We educate physicians on the clinical value of our assays through our information-oriented marketing campaigns. Through our specialized testing menu and efforts to educate physicians, we also generate significant revenues from other national and regional clinical laboratories and specialized physician practices. Our technical, experienced sales force concentrates on the hospitals and independent laboratories that serve as distribution channels for physician assay orders. We use our advanced information technology solutions to accelerate and automate electronic ordering and results reporting with these customers.

In 2001, we acquired BBI Clinical Laboratories, Inc. (BBICL). BBICL, founded in 1989, was a leading esoteric clinical reference laboratory specializing in infectious disease testing, such as Lyme disease and viral hepatitis. BBICL's primary customers included hospitals, physician specialists, pharmaceutical and diagnostic companies, and other clinical and research laboratories. Periodically, we evaluate the possibility of acquiring various clinical reference laboratories and entering into strategic technology licensing agreements.

Unilab Corporation, previously our largest customer prior to being acquired by Quest Diagnostics in 2003, comprised approximately 10% and 8% of our net revenue for the years ended December 31, 2002 and 2001, respectively. As a result of Unilab's acquisition, we experienced a significant decline in testing volumes sent to us from Unilab.

Relocation to Valencia, California facility

In December 2001, we purchased a 13.8 acre site in Valencia, California and began construction during the second quarter of 2002 of a 198,000 square foot facility, which would enable us to consolidate all of our laboratory and administrative functions in one location. In October 2002, we announced that we would postpone the move from our current Santa Monica, California location to our new facility in Valencia until the second half of 2004. Accordingly, the construction of the new facility was suspended at completion of the Core and Shell of the facility, which was substantially completed in January 2003. We resumed construction of the Valencia facility in early 2004. On February 11, 2004, we signed an agreement for the sale and leaseback of the Valencia facility with Lexington Corporate Properties Trust (Lexington), a real estate investment trust. Under the terms of the agreement, Lexington purchased the existing facility for \$47.0 million. We planned to complete the construction project and entered into a 20-year lease for use and occupancy of the facility. The sale and leaseback transaction was completed on March 18, 2004.

Lease payments began in September 2004. Based on interest rates in effect on August 31, 2004, rent expense for the new facility is expected to be approximately \$4.6 million per year, approximately \$2.0 million higher than comparable costs at the current facilities without any expansion, and includes the effect of scheduled rent increases in future years under our 20-year lease. We expect certain other operating expenses at the Valencia facility, such as utilities and property taxes, may also exceed current cost levels in Santa Monica by as much as \$2.0 million annually, based primarily on the considerably larger size of the Valencia facility.

During the third quarter 2004, we substantially completed construction activities and relocated our administrative functions from Santa Monica to our facility in Valencia. The move of our laboratory functions from the facilities in Santa Monica to Valencia is planned to be conducted in stages beginning in the fourth quarter of 2004 and we expect to complete the relocation in the first half of 2005. During the phased relocation process, Specialty anticipates some temporary duplication in operations-related costs between Santa Monica and Valencia as part of our effort to avoid service disruptions and assist in an efficient business transition. In addition, we expect to incur incremental costs during the relocation process of approximately \$2.5 million to \$3.0 million for overlapping rents and relocation expenses. The initial incremental relocation costs amounted to approximately \$486,000 during the third quarter 2004. The final timing and costs associated with the move and duplicate operations are contingent upon certain factors outside of our direct control, including final clearance by applicable state agencies. For more information, please see Risk Factors - Our planned move to a new facility in Valencia, California may divert management attention and may lead to disruptions in our operations and service to our customers and Risk Factors Regulatory requirements may affect our plans for a phased relocation to Valencia, California and increase our move-related costs.

Other significant developments in the last quarter included:

On September 15, 2004, we announced that Mr. Thomas R. Testman resigned from our Board of Directors. Mr. Testman also served on the Audit Committee and the Nominating/Corporate Governance Committee. Mr. Testman resigned for personal reasons.

On September 16, 2004, we announced the appointment of Mr. Richard K. Whitney to our Board of Directors to fill the vacancy resulting from Mr. Testman's resignation. Our Board of Directors also appointed Mr. Whitney to serve on the Audit Committee and the Regulatory Committee of our Board of Directors. Our Board of Directors has determined that Mr. Whitney is an independent director in accordance with the current listing standards of the New York Stock Exchange.

On September 29, 2004, we entered into a supplier agreement with Novation, the supply company of VHA, Inc. and the University HealthSystem Consortium (UHC). Under the agreement, we are named as one of three authorized providers to make reference testing services available to the more than 2,300 member health care organizations of VHA and UHC.

Critical Accounting Policies

Revenue Recognition

We recognize revenue for each customer order when the following fundamental criteria are met: (i) the testing process for a specific customer has been completed; (ii) we have no further performance obligation to the customer; (iii) the customer is obligated to pay for services rendered; and (iv) the related fees are non-refundable. Our revenue recognition policies are in compliance with Securities and Exchange Commission Staff Accounting Bulletin No. 101, *Revenue Recognition in Financial Statements*.

Services are provided to certain patients covered by various third-party payor programs including Medicare and Medicaid. Billings for services under third-party payor programs are included in net revenue net of allowances for differences between the amounts billed and estimated receipts under such programs. Adjustments to the estimated payment amounts based on final settlement with the third-party payor programs are recorded upon settlement.

Expense Recognition

Expenses are recognized as incurred and are generally classified between cost of services and selling, general and administrative expenses. The primary components of cost of services are salaries and employee benefits, research and development costs, supplies and reagents, equipment rental costs, courier costs, facilities related costs and depreciation of laboratory equipment and leasehold improvements. Selling, general and administrative expenses include salaries and employee benefits, sales and marketing, information technology, professional fees, insurance, facilities related costs, depreciation and bad debt expense.

Stock-Based Compensation Charges

Stock-based compensation charges represent the difference between the exercise price of options granted, or the price of stock sold to employees and directors, and the deemed fair value of our common stock on the date of grant or sale in accordance with Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees*, and its related interpretations. In the case of options, we recognize this compensation charge over the vesting periods of the options using an accelerated amortization methodology in accordance with Financial Accounting Standards Board Interpretation No. 28. For purposes of the period-to-period comparisons included in Results of Operations, selling, general and administrative expenses exclude these stock-based compensation charges, which are reflected as a separate line item.

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We have recorded deferred stock-based compensation related to unvested stock options granted to employees and directors. Based on the number of outstanding options granted as of September 30, 2004, we do not expect to amortize any deferred stock-based compensation during the remainder of 2004. We anticipate that the exercise price of the options granted after the calendar year of 2000 will be at the reported market price of our common stock, and therefore no deferred stock-based compensation will result from these grants.

Off-Balance Sheet Arrangements

There are no off-balance sheet transactions, arrangements or obligations (including contingent obligations) that have, or are reasonably likely to have a material effect on the Company's financial condition, changes in the financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources, except for the lease of our Valencia facility.

Results of Operations

The following table sets forth the percentage of net revenue represented by certain items in our consolidated statements of operations.

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|-------------------------------------|--------|------------------------------------|--------|
| | 2003 | 2004 | 2003 | 2004 |
| Net revenue | 100.0% | 100.0% | 100.0% | 100.0% |
| Cost of services | 71.5 | 69.1 | 72.3 | 69.4 |
| Selling, general and administrative (exclusive of stock-based compensation charges) | 39.8 | 39.0 | 37.5 | 36.5 |
| Operating loss | (11.4) | (8.1) | (9.9) | (6.0) |
| Loss from operations before income tax benefit | (10.9) | (7.8) | (9.3) | (5.6) |
| Net loss | (7.6) | (6.4) | (6.3) | (5.1) |

Quarter Ended September 30, 2004 Compared with Quarter Ended September 30, 2003*Net Revenue*

Net revenue of \$34.6 million for the quarter ended September 30, 2004 represents an increase of approximately \$4.7 million, or 16%, from the \$29.9 million for the prior year third quarter. This increase in revenues resulted primarily from an increase in accession volumes to approximately 782,000 for the third quarter of 2004, increasing more than 24% from the prior year third quarter volume of approximately 630,000. Testing volume for the third quarter included an unusual increase in independent laboratory business. This stream of work, which we believe may be temporary in nature, represented approximately 56,000 accessions and \$750,000 of the \$34.6 million in net revenues for the period. Excluding this new business, our accession volumes for the 2004 third quarter were approximately 726,000, representing an increase of more than 15% over the 2003 third quarter volume.

Sequentially, net revenues for the third quarter of 2004 increased from the second quarter of 2004 by approximately \$1.4 million or 4.3%, reflecting an increase in accession volumes to 782,000 from nearly 706,000 in the second quarter of 2004, representing an increase of approximately 11%. Excluding the accessions from our increased independent laboratory business, our sequential growth in accession volume from the second quarter was approximately 2.8%. The accession volume growth continues to reflect the increase in business from hospital

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clients and regional laboratories. Our aggregate average selling price for the third quarter 2004 appears lower than that of the first and second quarters of 2004. However, excluding the impact of the new independent laboratory business, our overall pricing was consistent with the preceding two quarters and remained a function of our pricing discipline combined with test and customer mix. The average aggregate selling price on our core business was down less than

1% from the second quarter 2004, and was essentially equal to the first quarter 2004, in line with our expectations. The key dynamic of our average selling price is the mix of tests which clients send us. As we bring on new accounts and expand our testing volume from existing accounts, we expect the broad mix of specialized testing work we may receive to exhibit some variability. The specific composition of this mix of tests can affect the relative proportion of higher and lower price testing that we perform. We expect pricing will remain consistent with its current level during the fourth quarter of 2004, as we continue efforts to increase test volumes. On a year over year basis, the growth of new business activity remains sound and, as a result, we expect accession volumes in the fourth quarter 2004 will range between 700,000 and 710,000. We project revenue of approximately \$132 million to \$135 million for the full year 2004.

Cost of Services

Cost of services, which includes costs for laboratory operations, distribution services, and research and development, increased \$2.6 million, or 12.1%, to \$23.9 million for the third quarter of 2004 from \$21.3 million for the comparable prior year quarter. This increase is due primarily to higher accession volumes, and resultant increases in costs for reagents and royalties, laboratory labor costs, and

distribution costs. No costs related to the Valencia facility or relocation are included in the costs of services for the third quarter 2004,

as we conducted all our laboratory operations in Santa Monica during the period. As a percentage of revenue, cost of services decreased to 69.1% for the quarter ended September 30, 2004 from 71.5% for the comparable prior year quarter. Although we experienced some positive trends in cost of services during the 2004 third quarter, we encountered several complications which adversely affected our costs of services. We experienced increased operating costs associated with certain transportation interruptions caused by the hurricanes on the East coast and temporary shutdowns of Los Angeles International Airport that resulted in laboratory inefficiencies and overtime charges. While we believe these factors did not have a material effect on our accession volumes, it did have an effect on our operations. Specimens did not arrive at our facilities at their scheduled times, causing us to deploy double work shifts in our laboratory and run less efficient batch sizes, utilizing more overtime and reagent materials. Costs associated with outsourced testing were also higher than in previous periods. However, having recently internalized a number of tests, we anticipate that outsourced testing should return to prior period levels and ultimately begin to decrease in future periods. In addition, start-up activities related to the temporary influx of independent laboratory work contributed to higher labor and reagent expense during the period. Our laboratory management team implemented several cost management initiatives from which we experienced some immediate benefits in the second quarter 2004. These initiatives did not produce the same benefits in the 2004 third quarter. As we continue the analysis of our usage and purchasing patterns, we expect our cost management initiatives to be more effective in future periods.

In comparing the third quarter of 2004 to the second quarter of 2004, costs of services increased approximately \$1.6 million or 7.4%. As a percentage of revenue, cost of services increased to 69.1% in the third quarter of 2004 from 67.1% for the quarter ended June 30, 2004. This increase in cost of services, both in absolute terms and as a percentage of revenue, is the result of the aforementioned complications which adversely affected our costs of services combined with higher accession volumes and the resultant increases in costs for reagents, royalties, laboratory labor costs, and distribution costs. For the fourth quarter 2004, exclusive of the effect of our laboratory move to our new Valencia facility, we expect that costs of services as a percentage of revenue will improve over the third quarter 2004 and will be closer to the results achieved in second quarter 2004. However, overall costs of services are difficult to forecast during the execution of our move in 2004 fourth quarter and 2005 first quarter. Some amounts that could be included in cost of services are not yet known. For example:

We will use significant amounts of reagents during testing validation required for the laboratory in Valencia. Some, if not all, of these reagent costs will affect cost of services.

In comparing the third quarter of 2004 to the second quarter of 2004, costs of services increased approximately \$1.

Double expenses may be incurred for the rental and usage of duplicate equipment and for double personnel shifts to validate the laboratory.

To the extent that we are performing actual testing in Valencia, a portion of the actual facility costs will be moved from SG&A to Cost of Services.

We are committed to minimizing any service disruptions to our clients during the laboratory move, and we will spend the amounts necessary to ensure that our service levels remain high over the course of this transition period.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased by \$1.6 million, or 13.6% to \$13.5 million for the third quarter of 2004 from \$11.9 million for the third quarter of 2003. As a percentage of revenue, selling, general and administrative expenses decreased to 39.0%

for the quarter ended September 30, 2004 from 39.8% for the comparable prior year quarter. Sequentially, selling, general and administrative expenses in the third quarter of 2004 increased nearly \$2.0 million, or 17.8%, from the second quarter of 2004. As a percentage of revenue, selling, general and administrative expenses increased to 39.0% for the quarter ended September 30, 2004 from

34.5% for the quarter ended June 30, 2004. There are four primary components included in the sequential and year-over-year increase in selling, general and administrative costs. First, this increase reflects approximately \$600,000 in direct costs related to our Valencia facility, including rent, depreciation on leasehold improvements and estimates for utilities and property taxes. The \$600,000 incurred in the third quarter 2004 does not represent an entire quarter of operating expenses, but expenses for approximately one to two months. After the move of the laboratory to Valencia, an appropriate portion of these costs will be reclassified to cost of services. Second, we increased our bad debt expense over historical rates by approximately \$800,000. This increase is related to collection difficulties experienced at one of our international clients, combined with lower than expected collections through the third quarter 2004 on account balances from 2003. The international client was active and paying regularly through the second quarter 2004, but encountered financial and operational difficulties during the 2004 third quarter. We now believe that they are unable to meet their financial obligations, and we have ceased performing testing for this client. Third, variable costs associated with volume increases, such as sales commissions and purchasing agreement fees, increased approximately \$500,000 over levels experienced during the second quarter 2004.

Finally, relocation costs of approximately \$486,000 were included in selling, general and administrative costs during the third quarter 2004. These relocation costs reflect the expense of moving our administrative operations to Valencia and shutting down our administrative offices in Santa Monica, including the physical move from Santa Monica, the accrual of the remainder of our lease obligation on our former administrative facility, the write-off of equipment and leasehold improvements in that former facility which will no longer be serviceable, and other miscellaneous relocation related expenses. As previously indicated, we anticipate that total expenses related to the facility relocation will range between \$2.5 million to \$3.0 million, the major portion of which will be incurred in fourth quarter 2004 and first quarter 2005, depending on the final timing of the relocation. Our relocation process began during the third quarter 2004 and is expected to continue during the fourth quarter 2004 and the first half of 2005.

For the fourth quarter 2004, exclusive of relocation costs, we expect that selling, general, and administrative expenses will range between \$13.0 million and \$14.0 million, reflecting a full quarter of costs associated with the Valencia facility, variable costs tied to volume growth, and increased investment in the training and development of the sales organization.

Selling, general and administrative expenses increased by \$1.6 million, or 13.6% to \$13.5 million for the third quarter

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Stock-Based Compensation Charges

Stock-based compensation charges decreased from approximately \$17,000 to \$1,000 from the third quarter of 2003 to the third quarter of 2004. The decline is the result of normal amortization expense during the period. As of September 30, 2004, stock-based compensation charges have been fully amortized.

Interest (Income) Expense, Net

Net interest income decreased from approximately \$145,000 for the third quarter 2003 to approximately \$89,000 for the third quarter 2004. The decrease in net interest income reflects the impact of lower interest rates earned on invested balances during 2004 that was partially offset by higher average investment balances resulting from the proceeds of our sale/leaseback agreement for our Valencia facility. Additionally, net interest income during the third quarter 2004 as compared to the prior year comparable quarter was reduced by higher interest expense related to outstanding debt balances under our line of credit. On September 24, 2004, we paid down the entire \$5.2 million borrowed against the line of credit, including approximately \$185,000 of accrued interest. Sequentially, net interest income decreased from \$177,000 for the second quarter 2004 to \$89,000 for the third quarter 2004. The decrease is primarily attributable to the aforementioned increase in interest expense related to outstanding debt balances under our line of credit that had been capitalized in connection with the construction of our Valencia facility during the first six months of 2004. The capitalization of interest expense ceased during the third quarter 2004 as we substantially completed construction activities at our Valencia facility.

Provision for Income Taxes (Benefits)

For the third quarter of 2004, we did not record any additional benefits for income taxes related to current operations due to considerations regarding the future utilization of existing deferred tax assets that are recorded in our balance sheet as of September 30, 2004. However, we did record an income tax benefit of \$501,000 related to the successful resolution of federal and state tax audits, which were ongoing since the end of 2003. For the third quarter of 2003, we recorded a benefit for income taxes of \$973,000. We do not expect to record any additional benefits for income taxes should they be available. If our loss narrows and we return to profitability, the effective tax rate could fluctuate significantly depending on the exact nature of the operating results. Please see Risk Factor Our effective tax rate may fluctuate and we may not be able to fully realize all or a portion of our deferred tax assets.

Net Loss

A net loss of \$2.2 million was recorded for the quarter ended September 30, 2004 compared to a net loss of \$2.3 million for the comparable prior year quarter. The increase in revenue that we experienced during the third quarter 2004 over the third quarter 2003 was offset by the aforementioned increases in cost of services, facilities costs for our Valencia facility, bad debt expense, variable costs associated with increased sales volume, and relocation expenses related to the move of our administrative functions. As a percentage of revenue, a net loss of 6.4% was recorded for the quarter ended September 30, 2004 as compared to a net loss of 7.6% for the comparable prior year quarter.

Nine Months Ended September 30, 2004 Compared with Nine Months Ended September 30, 2003

Net Revenue

Net revenue increased approximately \$10.0 million, or 11.2% to \$99.2 million for the nine months ended September 30, 2004 from \$89.2 million for the nine months ended September 30, 2003. Revenues for the current nine month period were impacted primarily by an increase in accession volumes to approximately 2,158,000 for the nine months ended September 30, 2004, an increase of more than 16.1% from volume of approximately 1,858,000 in the first nine months of 2003. The year-over-year increase in accession volume reflects the increase in business from hospital clients and regional laboratories. The significant decline in business referred from Unilab Corporation, our largest customer prior to their acquisition by Quest Diagnostics, occurred in the first quarter 2003. Beginning with the second quarter of 2004, the reduction of volume from Unilab does not have any material direct affect on the comparison with the prior year comparable quarter. Excluding the impact of the new independent laboratory increase of 56,000 accessions and \$750,000 in revenues, we experienced a decline of approximately 2.5% in the aggregate average selling price for the first nine months of 2004 as compared to the first nine months of 2003. This decline in aggregate average selling price was due primarily to changes in test mix sent to us by our clients and the loss of higher-priced tests received from Unilab in the first quarter of 2003.

Cost of Services

Cost of services, which includes costs for laboratory operations, distribution services, and research and development, increased \$4.3 million, or 6.6% to \$68.8 million for the first nine months of 2004 from \$64.5 million for the comparable prior year period. As a percentage of revenue, cost of services decreased to 69.4% for the nine months ended September 30, 2004 from 72.3% for the comparable prior year period. The decline in cost of services as a percentage of revenue is the result of the improvements in operational efficiency and cost management initiatives combined with economies of scale achieved through higher accession volumes during 2004.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased \$2.7 million or 8.1% to \$36.1 million for the first nine months of 2004 from \$33.4 million for the first nine months of 2003. The increase in selling, general, and administrative expenses is the result of the aforementioned bad debt adjustment, relocation costs, direct costs relating to the Valencia building and increased variable expenses related to higher sales volumes; combined with, the effect of annual salary and compensation adjustments which were implemented during the second quarter of 2004. As a percentage of revenue, selling, general and administrative expenses decreased to 36.5% for the nine months ended September 30, 2004 from 37.5% from the comparable prior year period.

Stock-Based Compensation Charges

Stock-based compensation charges increased from approximately \$52,000 recorded in the first nine months of 2003 to approximately \$147,000 recorded in the first nine months of 2004. The increase for the nine months ended September 30, 2004 compared to the nine months ended September 30, 2003 is primarily due to a charge related to the separation of our former chief financial officer and a related modification of his stock option award. As of September 30, 2004, stock based compensation has been fully amortized.

Interest (Income) Expense, Net

Net interest income decreased from approximately \$503,000 for the first nine months of 2003 to \$328,000 for the first nine months of 2004. The reduction in net interest income reflects the impact of lower interest rates earned on investment balances during 2004 combined with the aforementioned increase in interest expense related to outstanding debt balances under our line of credit.

Provision for Income Taxes (Benefits)

We did not record any additional benefits for income taxes related to current operations during the first nine months of 2004 due to considerations regarding the future utilization of existing deferred tax assets that were recorded in our balance sheet. During the first nine months of 2003, we recorded a \$2.7 million benefit for income taxes. However, we did record an income tax benefit of \$501,000 related to the successful resolution of federal and state tax audits, which were ongoing since the end of 2003. We do not anticipate recording any additional tax benefits on future losses during the remainder of 2004. Current and future net operating losses will only be realized when we attain profitability. If our loss narrows and we return to profitability, the effective tax rate could fluctuate significantly depending on the exact nature of the operating results. Please see Risk Factor Our effective tax rate may fluctuate and we may not be able to fully realize a portion of our deferred tax assets.

Net Loss

We recorded a net loss of \$5.1 million for the first nine months of 2004 compared to a net loss of \$5.6 million for the comparable prior year period. This resulted in an improvement of approximately \$512,000 or 9.1%. As a percentage of net revenue, a net loss of 5.1% was recorded for the nine months ended September 30, 2004 as compared to a net loss of 6.3% for the comparable prior year period.

Liquidity and Capital Resources

Our cash and cash equivalents combined with short-term and long-term investments totaled approximately \$43.6 million as of September 30, 2004 as compared to \$36.7 million as of December 31, 2003. This \$6.9 million increase is primarily related to the receipt of proceeds, net of \$1.6 million in financing related expenses, of \$41.9 million from the sale-leaseback transaction of our Valencia facility to Lexington Corporate Properties Trust on March 18, 2004, and partially offset by capital expenditures of \$22.8 million as we resumed construction of our Valencia facility, as reflected in investing activities during the nine months ended September 30, 2004. Our short-term and long-term investments, accounting for \$19.9 million, are almost entirely in corporate bonds and government securities.

During the third quarter of 2004, we substantially completed construction activities, relocated our administrative functions from Santa Monica to our Valencia facility and commenced making lease payments to Lexington on September 1, 2004. On September 15, 2004, we received approximately \$15.7 million of the \$19.2 million balance of proceeds. Receipt of the \$3.5 million balance of proceeds is expected during the fourth quarter of 2004, contingent upon the completion of certain deliverables to Lexington, including completion of the construction of the laboratory portion of the new facility. The \$3.5 million balance of proceeds has been recorded as a receivable in our balance sheet as of September 30, 2004.

The move of our laboratory functions from the facilities in Santa Monica to Valencia will be conducted in stages beginning in the fourth quarter of 2004 and we expect to complete the relocation in the first half of 2005. During the phased relocation process, we anticipate some temporary duplication in operations-related costs between Santa Monica and Valencia as part of our effort to avoid

service disruptions and assist in an efficient business transition. In addition, we expect to incur incremental costs during the relocation process of approximately \$2.5 million to \$3.0 million for overlapping rents and relocation expenses. These incremental relocation costs amounted to approximately \$486,000 during the third quarter 2004. The final timing and costs associated with the move and duplicate operations are contingent upon certain factors outside of our direct control, including final clearance by applicable state agencies. For more information, please see Risk Factors - Our planned move to a new facility in Valencia, California may divert management attention and may lead to disruptions in our operations and service to our customers and Risk Factors Regulatory requirements may affect our plans for a phased relocation to Valencia, California and increase our move-related costs.

Operating activities for the nine months ended September 30, 2004 used net cash of approximately \$8.0 million. The net decrease in the combined accounts payable and accrued liabilities used cash of approximately \$3.6 million, primarily for severance, payroll and vendor payments. The increase in accounts receivable resulted in the use of cash of \$3.5 million. The net loss of \$5.1 million was offset by depreciation and amortization of \$4.7 million and a \$190,000 reduction in inventory and prepaid expenses. For the nine months ended September 30, 2003, \$5.8 million of cash was provided by operating activities. The effect of income taxes was the primary contributor generating cash of approximately \$4.7 million, as \$7.8 million was provided by income tax refunds and tax benefits related to the exercise of employee stock options partially offset by approximately \$3.1 million of increases in deferred income taxes. The net increase of the combined accounts payable and accrued liabilities provided cash of approximately \$2.1 million. The net loss of \$5.6 million was offset by depreciation and amortization of \$5.0 million.

Investing activities during the first nine months of 2004 provided cash of \$9.7 million as we received \$41.9 million in proceeds, net of \$1.6 million in financing costs that is reflected in financing activities, from the sale of our Valencia facility to Lexington. This receipt was partially offset by \$22.8 million of capital expenditures as we resumed construction of the Valencia facility and also repositioned \$15.9 million of cash and cash equivalents to long-term investments. For the first nine months of 2003, investing activities used cash of \$6.3 million as we made capital expenditures to complete the Core and Shell phase of our Valencia facility, completed an information technology infrastructure upgrade for our existing facilities, and improved certain core client electronic ordering and results reporting applications.

Net cash used in financing activities was \$5.5 million for the first nine months of 2004 as compared to cash provided by financing activities of \$5.6 million for the first nine months of 2003. For the first nine months of 2004, we paid \$1.6 million in financing related expenses associated with the sale and leaseback of our Valencia facility and repaid approximately \$5.0 million of borrowings under our line of credit. These payments were partially offset by the combined receipt of \$1.2 million from the exercise of stock options and the sale of common stock to employees. For the first nine months of 2003, net cash was provided by financing activities from \$5.0 million of borrowings under our line of credit and the combined proceeds from the exercise of stock options and the sale of common stock to employees of \$843,000.

On September 24, 2003, we entered into a \$25 million asset-based credit agreement with CIT Business Credit (CIT), a unit of CIT Group Inc. The credit facility is secured primarily by accounts receivable, with the availability of funds based on the outstanding balance of this asset. The original credit agreement provided us with an initial \$15 million line of credit. On August 13, 2004, we entered into an amendment to our agreement with CIT whereby CIT agreed to assist us in obtaining letters of credit in an aggregate amount of up to \$10.1 million. The aggregate amount of outstanding letters of credit reduces the amount that we can borrow against our \$15.0 million line of credit. On September 14, 2004, CIT assisted us in obtaining a \$9.0 million irrevocable letter of credit with JPMorgan Chase Bank that names Lexington as the beneficiary. Lexington required us to post a security deposit in the form of a

letter of credit in connection with the lease agreement for our Valencia facility. The principal amount of borrowings was due three years from the closing date, the date the line of credit matures. Interest is computed and payable monthly. Interest is based on the Chase Bank rate plus one-half percent (0.5%) per annum. On September 24, 2004, we paid down the entire \$5.2 million borrowed against the line of credit, including approximately \$185,000 of accrued interest.

We expect existing cash and cash equivalents, short-term investments, and the balance of proceeds from the sale and leaseback arrangement will be sufficient to fund our operations, meet our capital requirements to complete the Valencia construction project, relocate our remaining operations from Santa Monica and support our current growth for the next year. Although we believe we have sufficient capital to fund our activities for at least the next twelve months, our future capital requirements may vary materially from those now planned. For more information, please see Risk Factors. We may need or elect to raise additional funds to fund our operations and activities beyond the next year or to consummate acquisitions of other businesses, assets or technologies.

Contractual Obligations

There have been no material changes to the contractual obligations described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2003 except as follows. On February 11, 2004, the Company entered into an agreement for the sale and leaseback of our Valencia facility with Lexington. For the first five years lease payments will be fixed at an annual rate of approximately \$3.5 million and will be adjusted every five years. Lease payments for years 6 through 10 will be the amount necessary to fully amortize the total project cost over 15 years at an interest rate equal to the sum of the then interpolated 15-year U.S. Treasury Bond rate plus 75 basis points. Payments will be increased 10% for years 11 through 15 with an additional 10% increase scheduled for years 16 through 20. The primary term for the lease is twenty years. We have three options to extend the term of the lease: two renewal options of five years each and a third renewal option for four years and six months. (Please see our Condensed Consolidated Financial Statements Note 9 and Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations Liquidity and Capital Resources for further discussion.)

In the table below, we set forth our estimated operating lease obligations, based on interest rates in effect on August 31, 2004, related to this new lease agreement. Some of the figures we include in this table are based on management's estimates and assumptions about these obligations, including their duration, the possibility of renewal, anticipated actions by third parties, and other factors. The estimates of future lease payments are subject to changes in the interpolated 15-year Treasury Rate, which has increased slightly since the sale and leaseback transaction was completed, and which can be expected to vary further prior to and during years 6 through 20 of the lease. Because these estimates and assumptions are necessarily subjective, the contractual obligations we will actually pay in future periods may vary from those reflected in the table.

| | Total | 2004 | Payments due by Period | | 2009 and Beyond |
|-----------------------------|-----------|----------|------------------------|-------------|-----------------|
| | | | 2005 - 2006 | 2007 - 2008 | |
| (amounts in thousands) | | | | | |
| Operating lease obligations | \$ 91,716 | \$ 1,188 | \$ 7,125 | \$ 7,125 | \$ 76,278 |

Risk Factors

Our operations and facilities are subject to stringent laws and regulations and if we are unable to comply, our business may be significantly harmed.

As a provider of healthcare-related services, we are subject to extensive and frequently changing federal, state and local laws and regulations governing licensure, billing, financial relationships, referrals, conduct of operations, purchases of existing businesses, cost-containment, direct employment of licensed professionals by business corporations and other aspects of our business relationships.

If we do not comply with existing or additional laws or regulations, or if we incur penalties, it could increase our expenses, prevent us from increasing net revenue, or hinder our ability to conduct our business. In addition, changes in existing laws or regulations, or new laws or regulations, may delay or prevent us from marketing our products or cause us to reduce our pricing.

Fraud and Abuse

Of particular importance to our operations are federal and state laws prohibiting fraudulent billing and providing for the recoupment of non-fraudulent overpayments, as a large number of laboratories have been forced by the federal and state governments, as well as by private payors, to enter into substantial settlements under these laws. Government investigations of clinical laboratories have been ongoing for a number of years and are expected to continue in the future. Written corporate compliance programs to actively monitor compliance with fraud laws and other regulatory requirements are recommended by the Department of Health and Human Services Office of the Inspector General and we have a program following the guidelines in place.

Federal and State Clinical Laboratory Licensing

The operations of our clinical laboratory are subject to a stringent level of regulation under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). For certification under CLIA, laboratories such as ours must meet various requirements, including requirements relating to quality assurance, quality control and personnel standards. Since we perform patient testing from all states, our laboratory is also subject to strict regulation by California, New York and various other states. We are accredited by the College of American Pathologists, a private accrediting agency, and therefore are subject to their requirements and evaluation. Our failure to comply with CLIA, state or other applicable requirements could result in various penalties, including restrictions on tests which the laboratory may perform, substantial civil monetary penalties, imposition of specific corrective action plans, suspension of Medicare payments and/or loss of licensure, certification or accreditation. Such penalties could result in our being unable to continue performing laboratory testing. Compliance with such standards is verified by periodic inspections and requires participation in proficiency testing programs.

In June and October 2001, we underwent unannounced inspections by CDHS representing both the State of California and acting as agent of CMS under CLIA. Based upon these inspections, and findings that we were permitting unlicensed personnel to perform and supervise clinical laboratory testing in violation of California law, in 2002 CDHS and CMS separately imposed sanctions, including notice of revocation of our CLIA certificate, cancellation of our approval to receive Medicare and Medicaid payments for services performed, and civil money penalties.

After filing supplemental documentation supporting our compliance with the applicable requirements with CDHS and CMS, CDHS conducted additional unannounced inspections, and we

provided additional documentation supporting our compliance with CDHS requirements. CDHS subsequently indicated that we were in substantial compliance with California clinical laboratory law, and CMS also notified us that it had deemed Specialty in compliance with all condition level requirements of CLIA. CDHS and CMS assessed civil money penalties in excess of \$700,000, and we did not challenge the penalties.

In May 2003, CDHS conducted an unannounced monitoring inspection of our laboratory facilities in conjunction with the imposed onsite monitoring for three years. The CDHS inspection found no material deficiencies related to the issues we faced in 2002, and found that we continued to maintain condition level compliance with state laboratory law.

We will be subject to additional future inspections. No assurances can be given that our facilities will pass all future inspections conducted to ensure compliance with federal or any other applicable licensure or certification laws. Any inability to comply with federal, state or other applicable regulations could result in substantial monetary penalties, suspension of Medicare and/or Medicaid payments and/or loss of licensure, certification or accreditation, and could divert a substantial amount of management's time and resources. In addition, substantial expenditures are required on an ongoing basis to ensure that we comply with existing regulations and to bring us into compliance with newly instituted regulations.

Food & Drug Administration

Neither the FDA nor any other governmental agency currently fully regulates the new assays we internally develop. Although the FDA previously asserted that its jurisdiction extends to tests generated in a clinical laboratory, it has allowed these tests to be run and the results commercialized without FDA premarket approval. In January 2003, the U.S. Department of Health and Human Services (HHS) indicated it is assessing the feasibility of regulating in-house genetic testing, and HHS recently created a new committee, the Secretary's Advisory Committee on Genetics, Health and Society, to take over and expand on the role of the former Secretary's Advisory Committee on Genetic Testing (SACGT). Our existing and future assays may be subject to federal regulatory approval similar to the pre-marketing approval process that the FDA applies to drugs and medical devices, or may be subject to other increased regulatory standards, which could have a negative effect on our business. If the FDA seeks to regulate in-house genetic testing, depending on the nature and scope of such regulation, it could have a detrimental effect on our business. We cannot predict the extent of future FDA regulation and there can be no assurance that the FDA will not consider testing conducted at a clinical laboratory to require premarketing clearance. Hence, we might be subject in the future to greater regulation, or different regulations, that could have a material effect on our finances and operations.

The FDA has also asserted that its jurisdiction includes the ability to inspect our facilities in connection with certain testing we do for blood donation and collection centers. An inspector from the FDA conducted an unannounced site inspection of our laboratory facilities in July and August 2003 in connection with this testing for blood centers. The FDA inspector's report of this inspection did not indicate any material issues or deficiencies of our facilities. However, we will likely be subject to future FDA inspections, and no assurances can be given that our facilities will satisfactorily pass all such inspections. Any inability to comply with applicable FDA regulations could result in substantial monetary penalties, revocation of our FDA registration, suspension or cancellation of our ability to conduct testing for blood donation and collection centers, and could divert a substantial amount of management's time and resources, and any such action could materially harm our business.

Anti-Kickback Regulations

Existing federal laws governing Medicare and Medicaid and other similar state laws impose a variety of broadly described restrictions on financial relationships among healthcare providers, including clinical laboratories. These laws include federal anti-kickback laws which prohibit clinical laboratories from, among other things, making payments or furnishing other benefits intended to induce the referral of patients for tests billed to Medicare, Medicaid or certain other federally funded programs. In addition, they also include self-referral prohibitions which prevent us from accepting referrals from physicians who have non-exempt ownership or compensation relationships with us as well as anti-markup and direct billing rules that may apply to our relationships with our customers. Sanctions for violations of these laws may include exclusion from participation in Medicare, Medicaid and other federal healthcare programs, and criminal and civil fines and penalties.

Fee-Splitting

The laws of many states prohibit physicians from sharing professional fees with non-physicians and prohibit non-physician entities, such as us, from practicing medicine and from employing physicians to practice medicine. If we do not comply with existing or additional regulations, or if we incur penalties, it could increase our expenses, prevent us from increasing net revenue, or hinder our ability to conduct our business. In addition, changes in existing regulations or new regulations may delay or prevent us from marketing our products or cause us to reduce our pricing.

Our accessions have declined in the past, and may decline again in future periods.

Because of uncertainty surrounding the sanctions imposed by CMS in 2002, questions about our clients' ability to bill for services we performed for them, and a reduction in the number of assays we offer, some of our clients suspended or stopped sending us specimens for testing. As a result, our total accessions declined in 2002 and 2003. While accession volumes rose in the three quarters of 2004, we cannot provide any assurances that our clients will continue sending us specimens for testing due to a variety of factors, including competition from other reference laboratories and our clients internalizing testing we now perform for them. We also cannot provide assurances that our accessions will continue increasing, and they may decline again. If our accessions decline again, or if they fail to continue increasing, it could materially adversely affect our business, financial condition, results of operations and prospects.

Some of our customers are also our primary competitors. If they reduce or discontinue purchasing our assays for competitive reasons, it will reduce our net revenue.

Some of our customers, such as Quest, LabCorp and ARUP, also compete with us by providing specialized testing services. They often refer assays to us that they either cannot or elect not to perform themselves. During 2002, we saw a significant decline in test volumes referred to us from our competitors. Sales to our competitors were approximately 4% of our net revenue for the years ended December 31, 2003 and 2002. These parties may decide not to refer assays to us because they wish to develop and market assays similar to ours, and we may experience a further decline in our net revenues from these competitors. For example, in April 2002, Quest announced that they had entered into a definitive agreement to acquire Unilab Corporation. As a result, we experienced a significant decline in testing volumes sent to us from Unilab. We experienced a significant reduction in volume from Quest, LabCorp, Mayo and ARUP in 2002 and 2003, and if these or other laboratories decide to reduce or discontinue purchases of our assays for competitive or other reasons, it will reduce the number of our accessions and reduce our net revenue.

The clinical laboratory industry is intensely competitive. If we are unable to successfully compete, we may lose market share.

The esoteric clinical laboratory industry is highly competitive. This industry is dominated by several national independent laboratories, but includes many smaller niche and regional independent laboratories as well. Our primary competitors include:

large commercial enterprises, such as Quest Diagnostics, or Quest, and Laboratory Corporation of America, or LabCorp, that offer a wide test and product menu on a national scale;

smaller niche laboratories like Prometheus Laboratories or Athena Diagnostics that focus on a narrow segment of the market for specialized testing and

institutions such as Mayo Medical Laboratories, or Mayo, and Associated Regional University Pathologists, or ARUP, that are affiliated with large medical centers or universities.

Large commercial enterprises, including Quest and LabCorp, have substantially greater financial resources and may have larger research and development programs and more sales and marketing channels than we do, enabling them to potentially develop and market competing assays. These enterprises may also be able to achieve greater economies of scale or establish contracts with payor groups on more favorable terms. Smaller niche laboratories compete with us based on their reputation for offering a narrow test menu. Academic and regional institutions generally lack the advantages of the larger commercial laboratories but still compete with us on a limited basis.

Any of our competitors may successfully develop and market assays that are either superior to, or are introduced prior to, our assays. If we do not compete effectively with other independent clinical laboratories, we may be unable to maintain or grow in relation to our competitors.

Intense competition and consolidation in our industry could materially adversely affect our business, financial condition, results of operations and prospects.

The clinical laboratory industry is intensely competitive and highly fragmented. Our current competitors include large national laboratories that offer a wide test and product menu on a national scale as well as smaller niche and regional organizations. Some of our large competitors have expanded, and may continue to expand, their competitive product offerings through acquisitions. For example, Quest, the nation's leading provider of diagnostic testing and related services for the healthcare industry, acquired American Medical Laboratories Incorporated, a national provider of esoteric testing to hospitals and specialty physicians, Clinical Diagnostics Services, Inc., a provider of routine and esoteric testing, and Unilab Corporation, a leading clinical testing laboratory. LabCorp acquired Dianon Systems Inc., a leading U.S. provider of anatomic pathology and oncology testing services. Acquisitions among existing and future competitors may allow them to rapidly gain greater market share. In addition, some of our customers refer assays to us that they cannot perform themselves. These customers may no longer need to refer assays to us if they develop assays similar to us through the acquisition of other esoteric laboratories. A loss of business and customers from such acquisitions could materially adversely affect our business, financial condition, results of operations and prospects.

Our quarterly operating results may fluctuate and this could cause our stock price to fluctuate or decline.

Our quarterly operating results have varied significantly in the past and may vary significantly in the future. If our quarterly net revenue and operating results fall below the expectations of securities analysts and investors, the market price of our common stock could fall substantially. Operating results vary depending on a number of factors, many of which are outside our control, including, but not limited to:

demand for our testing and ancillary services;

loss of a significant customer or group purchasing organization contract;

new assay introductions by competitors;

changes in our pricing policies or those of our competitors;

the hiring and retention of key personnel;

our ability, and that of our clients, to bill Medicare and Medicaid programs for our services;

changes in healthcare laws and regulations;

costs of reagents and supplies, as well as other operating costs;

costs related to acquisitions of technologies or businesses

the impacts of service disruptions as a result of our laboratory move to our new facility; and

the effect of litigation.

Due to these and other factors, results of operations and quarterly revenues are difficult to forecast, and we believe that period-to-period comparisons of our operating results are neither meaningful nor predictive of future performance. In one or more future quarters our results of operations may fall below the expectations of securities analysis and investors. In that event, the trading price of our common stock would likely decline.

In addition, the trading price of our common stock may materially decline regardless of our operating results and performance. The market price of our common stock has been subject to significant fluctuations since our initial public offering in December 2000. The stock market has experienced significant price and volume fluctuations that have affected the market prices of securities, particularly securities of clinical laboratory, biotechnology and other health care service companies. In the past, following periods of volatility in the market price of a particular company's securities, securities class action litigation has often been brought against that company. As previously announced, such securities claims were filed against us in May and June 2002. Litigation of this type is often expensive and diverts management's attention and resources, and we can provide no assurance that we will be successful in defending these actions. For more detailed description of the purported class-action securities claims filed against us, please see Part II. Item 1. Legal Proceedings below.

We plan to generally expand our sales and marketing, research and development and general and administrative efforts, which will lead to an increase in expenses. If our net revenue does not increase along with these expenses, our business, financial condition, results of operations, or cash flows could be materially harmed and operating results in a given quarter could be worse than expected.

For a more detailed description of our operating results, please see Management's Discussion and Analysis of Financial Condition and Results of Operations above.

Our net revenue will be diminished if payors do not authorize reimbursement for our services.

There has been and will continue to be significant efforts by both federal and state agencies to reduce costs in government healthcare programs and otherwise implement government control of healthcare costs. In addition, increasing emphasis on managed care in the U.S. may continue to put pressure on the pricing of healthcare services. Uncertainty exists as to the reimbursement status of new assays. Third party payors, including state payors and Medicare, are challenging the prices charged for medical products and services. Government and other third party payors increasingly are limiting both coverage and the level of reimbursement for our services. Third party insurance coverage may not be available to patients for any of our existing assays or assays we discover and develop. In 2001, 2002 and 2003, third party payors accounted for approximately 6.9%, 6.6% and 8.3%, respectively, of our net revenue. However, a substantial portion of the testing for which we bill our hospital and laboratory clients is ultimately paid by third party payors and we do not know the percentage of our net revenue that is indirectly derived from these payors. Any pricing pressure exerted by these third party payors on our customers may, in turn, be exerted by our customers on us. If government and other third party payors do not provide adequate coverage and reimbursement for our assays, our net revenue may decline.

Requirements for competitive bidding procurement of Medicare/Medicaid laboratory testing services could exclude us from providing testing to certain patients.

Proposals have been made to require competitive bidding procurement of Medicare laboratory testing services. The Centers for Medicare and Medicaid Services (CMS) has recently selected a vendor to begin a demonstration project of a competitive bidding for clinical laboratory services, although the project has not yet begun. At least one state competitive Medicaid bidding proposal was made in Florida, and later withdrawn, that would permit only one laboratory to provide services as the sole vendor under the contract, and it is possible that other future competitive bidding demonstration projects may also award the contract to a sole-source vendor. We can provide no assurances that future competitive bidding processes will allow us to compete successfully for the Medicare/Medicaid contracts. In the event that we are not successful in the competitive bidding process, or are otherwise not allowed to participate in such awarded competitive bidding contracts, we may not be reimbursed for testing we perform for Medicaid patients in these states. Any restriction on our ability to do testing for Medicare/Medicaid patients, or be reimbursed for testing we perform for such patients, could materially affect our revenue and business. Any restriction on our ability to do testing for Florida Medicaid patients could also significantly negatively affect the amount of business we receive from our Florida clients, as such clients might be less inclined to divide the work they send to outside reference laboratories. Loss of business from our Florida clients could materially affect our revenue and business.

Increasing restrictions in government-funded payment programs, and reductions in government-funded spending on laboratory testing reimbursement, could restrict or exclude us from providing testing to certain patients, and could materially affect our revenue and business.

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Recent state and federal budget constraints have forced cuts in many government-funded payment and reimbursement programs. For example, in 2004, California implemented a reduction of

approximately 10% in the reimbursement schedule for laboratory testing performed for Medi-Cal patients. Florida has recently proposed an alternative to a competitive bidding sole-source process that would reduce its fee schedule by 10%. Other states may make similar or larger reductions in reimbursement schedules. Such reductions could cumulatively have a material negative effect on our business and net revenue. Furthermore, some states are implementing increased restrictions on healthcare providers' access to such payment programs, including sole-source contracts and restrictions based on past regulatory issues. While we currently believe that such restrictions should not exclude us from participation in such programs, we can provide no guarantees that we will not be excluded from, or have reduced access to, such programs. For example, because of our past regulatory issues with the California Department of Health Services and the Centers for Medicare and Medicaid Services, we could be prohibited from bidding on certain bidding projects or proposals. In the event we are excluded from, or have reduced access to, any government-sponsored payment program, it could have material negative effect on our revenue and on our business.

Our effective tax rate may fluctuate and we may not be able to fully realize a portion of our deferred tax assets.

We reported \$6,184,000 of deferred income taxes (current and long-term) in the September 30, 2004 balance sheet, with approximately \$10,772,000 of this amount related to federal and state net operating loss carryforwards (NOLs). Statement of Financial Accounting Standards No. 109, *Accounting for Income Taxes*, requires that deferred tax assets be reduced by a valuation allowance if it is more likely than not that some portion of the deferred tax asset will not be realized. The Company's valuation allowance totaled approximately \$3.4 million at September 30, 2004. Realization of the NOLs generated through September 30, 2004 is dependent on Specialty's ability to generate approximately \$24.2 million of federal and \$28.6 million of state ordinary income in future years. However, we cannot provide any assurances that the NOLs will be realized. Inability to generate the necessary ordinary income, and our inability to realize the NOLs, could have a material adverse effect on our results of operations in future quarters. The federal NOLs begin expiring in 2024 and the state NOLs begin expiring in 2014.

If we lose key personnel or cannot recruit additional personnel, our business may suffer.

We depend substantially on the continued services and performance of our senior management, particularly Douglas S. Harrington, M.D., our chief executive officer and laboratory director, and certain other key personnel. While we have employment agreements with our executive officers, including Dr. Harrington and other members of our current senior management group, the loss of the services of any of these executive officers or other key employees could hurt our business.

Our future success also depends on our ability to identify, attract, hire, train, retain and motivate other highly skilled technical, managerial, marketing and customer personnel, including California licensed laboratory scientists. Competition for such personnel is intense. We may not be able to attract, assimilate or retain sufficient qualified personnel. In particular, we may encounter difficulties in attracting a sufficient number of qualified California licensed laboratory scientists. Additionally, we may not be able to retain and attract necessary highly skilled technical, managerial, marketing and customer personnel at our new laboratory and operational headquarters facility in Valencia, California, which is approximately 30 miles from our current laboratory location in Santa Monica, California. Any failure to retain and attract necessary personnel could hurt our business and impair our growth strategy.

Our planned move to a new facility in Valencia, California may divert management attention and may lead to disruptions in our operations and service to our customers.

We have constructed a 198,000 square foot facility in Valencia, California that will enable us to consolidate our laboratory and administrative functions in one location. The location of the new facility is approximately 30 miles from our current laboratory location in Santa Monica, California.

While the majority of our administrative functions were successfully moved from Santa Monica in August 2004, and we did not experience any significant problems, moving our entire laboratory to a new location is a time-consuming and complicated process, and includes physically moving and setting up delicate and complex laboratory equipment over a short period of time, transferring specimens and reagents from one facility to another, changing processes and procedures for delivery of testing specimens, ensuring that we have adequate staffing of laboratory and administrative personnel at the new facility, and continuing to conduct our testing of specimens during the process. While we have announced a phased relocation to minimize client disruption, if we are unable to execute the move to Valencia effectively and efficiently, it could result in service disruptions that would negatively affect our business and could reduce our revenue. Such service disruptions could also result in customer dissatisfaction, and could materially hurt our business if our customers decided not to purchase our services any longer as a result of the service disruptions. Furthermore, planning for the move of our facility is also expected to divert the attention of key management personnel, as state laboratory licensing regulations in California make a phased relocation more complicated from a licensing perspective than moving the entire laboratory at once.

We can provide no assurances that key management will not be distracted by planning for the laboratory move. We can also provide no assurances that we will be able to complete the laboratory move to the new Valencia facility efficiently or effectively, or on time, or that we will not experience service disruptions, loss in customers, or decreased revenue as a result of the move. Because the new Valencia facility is located 30 miles away from our current headquarters, some of our key employees may choose not to remain employed with us after the move. The occurrence of any of the foregoing events affecting or resulting from our move could harm our business.

Regulatory requirements may affect or significantly delay our plans for a phased relocation to Valencia, California and increase our move-related costs.

Representatives of the State of California, Department of Health Services have previously stated that they may enforce certain purported requirements for assay validation and on-site inspection of each assay we perform prior to our being allowed to begin patient testing at our new Valencia laboratory facility. While we have received clarification from the state representatives, we have not yet received final approval from the state regarding our phased relocation plan.

If the Department of Health Services enforces these requirements, our phased relocation plan could be significantly affected. Staffing of state laboratory inspectors has been significantly affected by budgetary cuts, and the number of inspectors has been drastically decreased over the last several years. We may be forced to establish redundant laboratory systems in Valencia on a temporary basis to avoid any service disruptions to our clients. We may also be forced to significantly delay the laboratory portion of our phased relocation pending approval from the state regulators of our phased plans. Alternatively, to avoid redundancy and duplicative costs, we may need to increase the number of tests we send out to other laboratories while our phased relocation to the Valencia facility is conducted. We can provide no assurances that the State of California will not impose such validation and inspection requirements.

Implementing any redundant testing, any delay in our relocation timing, and any increase in our test send-outs could significantly increase the anticipated costs associated with our relocation, including the costs of redundant equipment, personnel, and supplies, and possible extensions of our leases for our buildings in Santa Monica. Such increased costs could significantly harm our business.

If group purchasing organizations do not renew and maintain our contracts, we may lose an important mechanism by which to further penetrate the hospital customer base.

Many of our existing and potential hospital customers are part of group purchasing organizations, which typically pool independent hospitals together to negotiate for pricing and services, including prices for laboratory tests. These group purchasing organizations provide incentives to their participating hospitals to utilize clinical laboratories which have contracts with the group purchasing organizations.

Our participation in group purchasing organizations constitutes one aspect of our overall strategy to attract new hospital customers. We have contracts with several group purchasing organizations: AmeriNet, Consorta, MedAssets HSCA (formerly Health Services Corporation of America), Managed Healthcare Associates (MHA), Novation, Premier Purchasing Partners, and Shared Services Healthcare (now affiliated with MedAssets HSCA). We are typically granted non-exclusive provider status under these contracts. Our contracts with our group purchasing organizations will expire at various times from 2004 to 2007.

If our agreement with any group purchasing organization is terminated or not renewed, we may not be able to retain any of the accounts of their participating hospitals. If any hospital customer affiliated with a group purchasing organization no longer uses our services, it will reduce our net revenue. In addition, if we are unable to attract new hospital customers because any group purchasing organization contract is terminated, it may adversely affect our ability to grow our business.

If advances in technology allow others to perform assays similar to ours, the demand for our assays may decrease.

The field of specialized clinical laboratory testing is characterized by advancing technology which may enable other clinical laboratories, hospitals, physicians or other medical providers to perform assays with properties similar to ours in a more efficient or cost-effective manner than is currently possible. Such technological advances may be introduced by, not just our competitors, but by any third party. For instance, a diagnostic manufacturing company may release an instrument or technology that would make it cost-effective for our customers to perform complex assays internally, rather than through us. If these or other advances in technology allow other entities to perform testing we currently perform, it could result in a decreased demand for our assays, and our assay volume and net revenue would decline. We may also be forced to lower prices on our assays to reduce the likelihood that other entities, including our clients, will perform such testing. Any assay volume, test price or revenue reductions would significantly harm our business.

If we do not comply with laws and regulations governing the confidentiality of medical information, it will adversely affect our ability to do business.

The confidentiality of patient medical information is subject to substantial regulation by the state and federal governments. State and federal laws and regulations govern both the disclosure and the use of confidential patient medical information. Most states have laws that govern the use and disclosure of patient medical information and the right to privacy. Similarly, many federal laws also may apply to

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protect such information, including the Electronic Communications Privacy Act of 1986 and federal laws relating to confidentiality of mental health records and substance abuse treatment.

Legislation governing the dissemination and use of medical information is continually being proposed and enacted at both the state and federal levels. For example, the Health Insurance Portability and Accountability Act of 1996, known as HIPAA, and regulations promulgated under HIPAA require certain healthcare providers and holders or users of electronically transmitted patient health information to implement measures to maintain the security and privacy of such information. Ultimately, this and other legislation may even affect the dissemination of medical information that is not individually identifiable. Physicians and other persons providing patient information to us are also required to comply with these laws and regulations. If a patient's privacy is violated, or if we are found to have violated any state or federal statute or regulation with regard to the confidentiality, dissemination or use of patient medical information, we could be liable for damages, or for civil or criminal fines or penalties. The HIPAA regulations required that covered entities (including us) be in compliance with the privacy regulations on or before April 14, 2003.

The commercialization of our Internet products including Outreach Express®, DataPassportMD®, and DataPassport Clinical Trials is strictly governed by state and federal laws and regulations, including the regulations under HIPAA. We have implemented encryption technology to protect patient medical information, however, use of encryption technology does not guarantee the privacy and security of confidential information.

We believe that we are in material compliance with all currently applicable state and federal laws and regulations governing the confidentiality, dissemination and use of medical record information. However, differing interpretations of existing laws and regulations, or the adoption of new laws and regulations, could reduce or eliminate our ability to obtain or use patient information which, in turn, could limit our ability to use our information technology products for electronically transmitting patient data. While we believe we are in compliance in all material respects with the applicable HIPAA regulations, our failure to comply could subject us to fines and penalties, and have a detrimental effect on our business. We may be subject to inspections or investigations by state or federal regulatory entities that enforce privacy laws and regulations, and we can provide no assurances that we will be found fully compliant with HIPAA or other privacy laws and regulations. Any findings of non-compliance with HIPAA or other privacy laws and regulations could significantly harm our client's confidence in abilities, and could significantly harm our business.

The premium prices that we initially charge for new assays may drop if our competitors are able to develop and market competing assays more quickly than they currently do.

Typically, we market new specialized assays at premium prices for several years before similar assays are developed as either standardized prepared kits for broad application or as internally developed assays by competing laboratories. The opportunity to sell our products at premium prices may be reduced or eliminated if our competitors are able to develop and market competing assays more quickly than they currently do. We may also be forced to lower prices on our assays to reduce the likelihood that other entities, including our clients, will perform testing we currently perform for them.

Our average selling price has fluctuated, and may go down depending on the ordering patterns of our clients.

As our clients internalize some tests we perform for them, or as they find alternative sources of testing, they may change the mix of testing sent to us. If our clients send us fewer higher-priced tests, the average selling prices for our assays could drop, and our revenue can be negatively affected. Our average

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selling price has gone down previously, and we can provide no guarantees that it will grow in the future, and it may go down again. Our business and potential profitability could be significantly affected if we are not able to grow our average selling price.

If we are unable to develop and successfully market new assays or improve existing assays in a timely manner, our profit margins may decline.

In order to maintain our margins and benefit from the premium prices that we typically charge for our newly introduced specialized assays, we must continually develop new assays and improve our existing assays through licensing arrangements with third parties and through the efforts of our R&D department. There is no assurance, however, that we will be able to maintain our current pace of developing and improving assays in the future. Even if we develop such assays in a timely manner, our customers may not utilize these new assays. If we fail to develop new technologies, release new or improved assays on a timely basis, or if such assays do not obtain market acceptance, our profit margins may decline.

If we fail to acquire licenses for new or improved assay technology platforms, we may not be able to accelerate assay improvement and development, which could harm our ability to increase our net revenue.

Our ability to accelerate new assay development and improve existing performance will depend, in part, on our ability to license new or improved assay technology platforms on favorable terms. We may not be able to negotiate acceptable licensing arrangements and we cannot be certain that such arrangements will yield commercially successful assays. Further, even if we enter into such arrangements with these third parties, their devotion of resources to these efforts may not be within our control or influence. If we are unable to license these technologies at competitive rates, our research and development costs may increase. In addition, if we are unable to develop new or improved assays through such research and development efforts, our assays may be outdated when compared with our competitors' assays, and our net revenue may decrease.

Failure in our information technology systems could significantly increase turn-around time, reduce our production capacity, and otherwise disrupt our operations, which may reduce our customer base and result in lost revenue.

Our success depends, in part, on the continued and uninterrupted performance of our information technology systems, including our DataPassport®, Data PassportMD® and Outreach Express® suite of products. Sustained or repeated system failures that interrupt our ability to process assay orders, deliver assay results or perform assays in a timely manner would reduce significantly the attractiveness of our products to our customers. Our business, financial condition, results of operations, or cash flows could be materially and adversely affected by any damage or failure that interrupts or delays our operations, or that reduces the attractiveness of our products to our customers.

Our computer systems are vulnerable to damage from a variety of sources, including telecommunications failures, malicious human acts and natural disasters. Moreover, despite reasonable security measures we have implemented, some of our information technology systems are potentially vulnerable to physical or electronic break-ins, computer viruses and similar disruptive problems, in part because we conduct business on the Internet and because some of these systems are located at third party web hosting provider, Qwest Communications in Burbank, California, and we cannot control the maintenance and operation of the Qwest data centers. Despite the precautions we have taken, unanticipated problems affecting our systems could cause interruptions in our information technology systems, leading to lost revenue, deterioration of customer confidence, or significant business disruption.

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Our average selling price has fluctuated, and may go down depending on the ordering patterns of our clients.

Our business, financial condition, results of operations, or cash flows could be materially and adversely affected by any problem that interrupts or delays our operations.

While we have insurance policies that may cover losses arising from such interruptions, these insurance policies may not adequately compensate us for any losses that may occur due to any failures in our systems as a result of moving to a new provider, or any losses that may occur due to any failures in our information technology systems.

If we lose our competitive position in providing valuable information technology solutions as an ancillary service to our customers, we may not be able to maintain or grow our business.

Over the past five years, we have made a substantial investment in our information technology solutions, such as DataPassport®, DataPassportMD®, and Outreach Express®, to facilitate electronic assay ordering and results reporting as a value added service for our customers. We believe that these solutions are one factor considered by our customers when selecting a reference laboratory. In the future, our competitors may offer similar or better information technology solutions to our existing and potential customer base. If this occurs, we may lose this competitive advantage, and as a result, may be unable to maintain or increase our business growth.

We rely on a few assays for a significant portion of our net revenue. If demand for these assays were to weaken for any reason, our net revenue would decrease.

A significant portion of our net revenue is derived from 30 assays. Net revenue from these 30 assays comprised approximately 45% of our total net revenue for the year ended December 31, 2003. If competing assays are introduced by competitors or demand for these assays otherwise decreases, our net revenue could decrease.

Clinicians or patients using our products or services may sue us and our insurance may not sufficiently cover all claims brought against us, which will increase our expenses.

The development, marketing, sale and performance of healthcare services expose us to the risk of litigation, including professional negligence. Damages assessed in connection with, and the costs of defending, any legal action could be substantial. We currently maintain insurance with coverage up to \$15 million, either singly or in the aggregate, which we believe to be adequate to cover our exposure in our current professional liability claims and employee-related matters which were incurred in the ordinary course of business. Although we believe that these claims may not have a material effect on us, because we expect them to be covered by this insurance, we may be faced with litigation claims which exceed our insurance coverage or are not covered under our insurance policy. In addition, litigation could have a material adverse effect on our business if it impacts our existing and potential customer relationships, creates adverse public relations, diverts management resources from the operation of the business or hampers our ability to perform assays or otherwise conduct our business.

If protection of the intellectual property underlying our technology and trade secrets is inadequate, then third parties may be able to use our technology or similar technologies, thus reducing our ability to compete.

Our average selling price has fluctuated, and may go down depending on the ordering patterns of our clients.

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We currently rely on certain technologies for which we believe patents are not economically feasible and therefore may be developed independently or copied by our competitors. Furthermore, we rely on certain proprietary trade secrets and know-how, which we have not patented. Although we have taken steps to protect our unpatented trade secrets and know-how, principally through the use of confidentiality agreements with our employees and consultants, there can be no assurance that these

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agreements will not be breached, that we would have adequate remedies for any breach, or that our trade secrets will not otherwise become known or be independently developed or discovered by competitors. If our trade secrets become known or are independently developed or discovered by competitors, it could have a material adverse effect on our ability to compete.

Our assays may infringe on the intellectual property rights of others, which may cause us to engage in costly litigation and/or enter into appropriate licenses which may cause us to pay substantial damages or royalties, and could prohibit or restrict us from selling our assays.

Other companies or institutions engaged in assay development, including our competitors, may obtain patents or other proprietary rights that would prevent, limit or interfere with our ability to develop, perform or sell our assays. As a result, we may be found to be, or accused of, infringing on the proprietary rights of others. For example, in response to a patent infringement allegation from Athena Diagnostics in 1997, we ceased performing an assay used to diagnose late onset Alzheimer's disease.

We also received letters from Chiron Corporation (Chiron) in February 1998, and the National Institute of Health (NIH) in 2000-2003 claiming that some of our assays may violate their patents. In August 2003 we reported that we had entered into a letter agreement with Chiron that called for us to make payments to Chiron for alleged past infringement of Chiron patents by certain Hepatitis C Virus (HCV) and Human Immunodeficiency Virus (HIV) testing performed by us, and Chiron agreed not to assert its patent rights, or bring any claim against Specialty for any alleged infringement relating to nucleic acid clinical assays for the detection, quantitation, genotyping and/or phenotyping of HCV and HIV occurring at any time prior to October 15, 2003. We cannot provide any assurances that the NIH or other patent holders will not bring suit against us in the future for alleged patent infringement. We intend to defend any such suit that may arise vigorously and to assert all available defenses to allegations of patent infringement that would be available to us.

In June 2004 we became aware of a lawsuit filed against us in the U.S. District Court for the Southern District of California by Prometheus Laboratories, Inc. (Prometheus). The complaint alleged infringement of Prometheus' patent rights by a new assay we announced for the monitoring of drug levels in connection with the treatment of Inflammatory Bowel Disease. Based partly on the threat of the litigation, and the service disruption the lawsuit could have on our clients, we chose not to make this new assay available to our clients, and the matter with Prometheus was resolved without admission of liability or the payment of any settlement amounts. Prometheus has since dismissed their lawsuit against us.

Patent infringement suits can be very expensive to defend and could divert management's time and resources, regardless of the merit or validity of any such suit. Furthermore, we cannot provide any assurances that we would be successful in defending any such suit, and there can be no assurance that there will be no adverse consequences to us. As a result of these claims and any other infringement related claims, we could incur substantial costs in defending any litigation, and such litigation, or the threat of such litigation, could force us to do one or more of the following:

cease developing, performing or selling products or services that incorporate the challenged intellectual property;

obtain and pay for licenses from the holder of the allegedly infringed intellectual property right; or

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redesign or reengineer our assays.

We can provide no assurances that we will be able to secure licenses for such patents on commercially reasonable terms, if at all. Licenses for such patents may require the payment of material sums of money as license fees and royalties, including fees and royalties for past infringement. Any efforts to reengineer our assays or any inability to sell our assays, or an obligation to pay license fees and royalties could substantially increase our costs, force us to interrupt product sales, delay new assay releases, decrease our competitiveness in the marketplace, reduce our revenues, and materially impair our business. In addition, if a suit were brought against us alleging patent infringement, and we were found to have infringed the patents at issue, we could be forced to pay substantial damages, including possible treble damages for allegations of willful infringement. While we intend to defend any such suit vigorously, and assert all available defenses, we cannot provide any assurances that we would be successful in defending any such suit. If we were to lose such a suit, it could create a material financial liability, negatively affect our operating results, and negatively impact our stock price.

We may acquire other businesses, products or technologies in order to remain competitive in our market and our business could be adversely affected as a result of any of these future acquisitions.

We have made in the past and we may continue to make acquisitions of complementary businesses, products or technologies. For example, we acquired BBI Clinical Laboratories, Inc. in February 2001. If we identify any additional appropriate acquisition candidates, we may not be successful in negotiating acceptable terms of the acquisition, financing the acquisition, or integrating the acquired business, products or technologies into our existing business and operations. Further, completing an acquisition and integrating an acquired business will significantly divert management time and resources. The diversion of management attention and any difficulties encountered in the transition and integration process could harm our business. If we consummate any significant acquisitions using stock or other securities as consideration, our shareholders' equity could be significantly diluted. If we make any significant acquisitions using cash consideration, we may be required to use a substantial portion of our available cash. Acquisition financing may not be available on favorable terms, if at all. In addition, we may be required to amortize significant amounts of other intangible assets in connection with future acquisitions, which would harm our operating results.

We may need or elect to raise additional funds to fund our operations and activities beyond the next year or to consummate acquisitions of other businesses, assets or technologies.

While we expect existing cash and cash equivalents, short-term investments, and lines of credit will be sufficient to fund our operations, meet our capital requirements to complete the Valencia construction project, relocate our operations from Santa Monica, support our growth, and allow strategic technology licensing and acquisitions for the next year, and we believe we have sufficient capital to fund our activities for at least the next twelve months, our future capital requirements may vary materially from those now planned. It is possible that we may need or elect to raise additional funds to fund our activities beyond the next year or to consummate acquisitions of other businesses, assets or technologies. We could raise such funds by selling additional equity securities to the public or to selected investors, or by borrowing money. In addition, even though we may not need additional funds, we may still elect to sell additional equity securities or obtain credit facilities for other reasons. We cannot assure you that we will be able to obtain additional funds on commercially favorable terms, or at all. If we raise additional funds by issuing additional equity or convertible debt securities, the ownership percentages of existing shareholders would be reduced. In addition, the equity or debt securities that we issue may have rights, preferences or privileges senior to those of the holders of our common stock.

We may encounter problems or delays in operating or implementing our automated processing systems, which could disrupt our operations, require us to develop alternatives and increase our costs.

In order to meet growth in demand for our specialized assays, we will have to process many more patient samples than we are currently processing. We have implemented a high-speed specimen sorting system known as the Total Accessioning Re-Organization System, or TARO , and a specimen splitting system, known as the Harmonized Assignment of Nanoliter Aliquots, or HANA . In addition, we plan to develop and implement other automated systems to enhance our testing procedures. We will need to develop sophisticated software to support these other automated procedures, analyze the data generated by these tests and report the results. Further, as we attempt to increase the number of patient samples we process, throughput or quality-control problems may arise.

If we are unable to consistently process patient samples on a timely basis because of delays or failures in our implementation of these automated systems, or if we encounter problems with our established automated processes, we will be required to develop alternate means to process our business which may increase our costs.

If a catastrophe were to strike our clinical laboratory facility, we would be unable to process our customers' samples for a substantial amount of time and we would be unable to operate our business competitively.

Our specimen processing facilities, our clinical laboratory, and our corporate offices may be affected by catastrophes such as fires, earthquakes or sustained interruptions in electrical service. Earthquakes are of particular significance to us because our current clinical laboratory facilities are located in Santa Monica, California, an earthquake-prone area. Our new Valencia facility is also in an earthquake-prone area. In the event our existing facilities or equipment are affected by man-made or natural disasters, we may be unable to process our customers' samples in a timely manner and unable to operate our business in a commercially competitive manner. To address these risks, we have in place formal recovery plans for such interruptions of service. This includes identification of alternate laboratory testing facilities and disaster recovery protocols. We also carry earthquake insurance with a coverage amount of up to \$20 million and we have outsourced part of our data storage and processing equipment to a facility designed to withstand most earthquakes. Despite these precautions, the self-insured retention amount for earthquake insurance is very high, and there is no assurance that we could recover quickly from a serious earthquake or other disaster.

We rely on a continuous power supply to conduct our operations, and California's energy crisis could disrupt our operations and increase our expenses.

Our specimen processing facilities, our clinical laboratory, and our corporate offices are located in Santa Monica and Valencia, California. California is still in an energy crisis that could disrupt our operations and increase our expenses. In the event power reserves for the state of California fall to critically low levels, California may implement rolling power blackouts throughout the state. The state of California has already experienced such occasional power blackouts. We currently have backup power generators for our laboratories in the event of a blackout. Our current insurance, however, does not provide coverage for any damages we may suffer as a result of any interruption in our power supply. If blackouts interrupt our third party power supply, we may be temporarily unable to continue operations. Any such interruption in our ability to continue operations would delay our processing of laboratory samples, disrupt communications with our customers and suppliers and delay product shipment. Power interruptions could also damage our reputation and could result in lost revenue. Any loss of power could

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have a material adverse effect on our business, operating results and financial condition. Furthermore, shortages in wholesale electricity supplies have caused power prices to increase. If wholesale prices continue to increase, our operating expenses will likely increase which will have a negative effect on our operating results.

Disruption similar to the September 2001 terrorist attacks in the future on the U.S. may adversely impact our results of operations, future growth and stock price.

The operation of our laboratories has been and may continue to be harmed by the recent terrorist attacks on the U.S. For example, transportation systems and couriers that we rely upon to receive and process specimens have been, and may in the future be, disrupted. In addition, we may experience a rise in operating costs, such as costs for transportation, courier service, insurance and security. We may also experience delays in receiving payments from payors that have been affected by the attack, which, in turn, would harm our cash flow. The U.S. economy in general may be adversely affected by the terrorist attacks or by any related outbreak of hostilities. Any such economic downturn could adversely impact our results of operations, revenues and costs, impede our ability to continue to grow our business and may result in the volatility of the market price of our common stock and on the future price of our common stock.

We may be unable to comply with certain requirements and deadlines of the Sarbanes-Oxley Act of 2002 relating to internal controls and procedures.

Section 404 of the Sarbanes-Oxley Act of 2002 requires that we undertake a detailed assessment of our internal controls and procedures, including an analysis, evaluation and testing. We have completed the evaluation of the design phase and have begun the testing phase of our project. As of September 30, 2004 we had not identified any potential control deficiencies. However, we can provide no assurances that we will be able to complete our testing by the required deadlines. We also cannot guarantee that we will not identify any potential or material control deficiencies before the end of our fiscal year and that we will be able to remediate in a timely manner any potential control deficiencies that may be identified. Furthermore, we cannot provide any assurances that any potential control deficiencies that may be identified will not rise to the level of significant deficiencies or material weaknesses. If we are unable to comply with any of the requirements of Section 404 of the Sarbanes-Oxley Act of 2002, including completing our assessment in a timely manner or the identification of any potential or material weaknesses in our internal controls or procedures, this would require appropriate public disclosure. Such disclosure could result in a decline in the trading price of our common stock and the loss of all or part of your investment, and could result in litigation being brought against the Company. Litigation of this type is often expensive and diverts management's attention and resources, and we can provide no assurance that we would be successful in defending these actions.

We are controlled by a single existing shareholder, whose interests may differ from other shareholders' interests.

Our principal shareholder is the Specialty Family Limited Partnership, whose sole general managing partner, James B. Peter, M.D., Ph.D., is a member of our board of directors. Specialty Family Limited Partnership, together with Dr. Peter, currently beneficially own approximately 61% of the outstanding shares of our common stock. Accordingly, the Specialty Family Limited Partnership along with Dr. Peter will have significant influence in determining the outcome of any corporate transaction or other matter submitted to the shareholders for approval, including election of directors, mergers, consolidations and the sale of all or substantially all of our assets. Our principal shareholder will also have the power to prevent or cause a change in control. The interests of this shareholder may differ from other shareholders' interests. In addition, this concentration of ownership may delay, prevent, or deter a

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change in control and could deprive other shareholders of an opportunity to receive a premium for their common stock as part of a sale of our business.

Anti-takeover provisions in our charter documents could prevent or delay a change in control and, as a result, negatively impact our shareholders.

We have taken a number of actions that could have the effect of discouraging a takeover attempt. For example, provisions of our amended and restated articles of incorporation and amended and restated bylaws could make it more difficult for a third party to acquire us, even if doing so would be beneficial to our shareholders. These provisions also could limit the price that certain investors might be willing to pay in the future for shares of our common stock.

These provisions include:

limitations on who may call special meetings of shareholders;

advance notice requirements for proposing matters that can be acted upon by shareholders at shareholder meetings; and

the ability of our board of directors to issue preferred stock without shareholder approval.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISKS

At any time, fluctuations in interest rates could affect interest earnings on our cash and cash equivalents and interest expense on our existing line of credit. We believe that the effect, if any, of reasonably possible near term changes in interest rates on our financial position, results of operations, and cash flows would not be material. Currently, we do not hedge these interest rate exposures. The primary objective of our investment activities is to preserve capital. We have not used derivative financial instruments in our investment portfolio.

At September 30, 2004, our holdings, which had an original maturity date of less than 90 days, were classified as cash and cash equivalents on our consolidated balance sheet. At September 30, 2004, we had cash and cash equivalents of \$23.7 million, which had a weighted average yield of 1.83% per annum. At September 30, 2004, our short-term investment balance of \$4.0 million, consisting of corporate bonds and government securities with maturity dates less than one year, had a weighted average yield per annum of 3.37% and an average of 51.5 days until maturity. At September 30, 2004, our long-term investment balance of \$15.9 million consisted of government securities with maturity dates beyond one year had a weighted average yield per annum of 2.56% and an average of 27.2 months until maturity.

ITEM 4. CONTROLS AND PROCEDURES

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by Rule 13a-15(b) of the Securities Exchange Act of 1934, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the quarter covered by this report. Based on the foregoing, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

There has been no change in our internal controls over financial reporting during the most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal controls over financial reporting.

As required by Section 404 of the Sarbanes-Oxley Act of 2002, we have been undertaking a detailed assessment of our internal controls and procedures. We have completed the evaluation of the design phase and have begun the testing phase of our project. As of September 30, 2004 we had not identified any potential control deficiencies. However, we can provide no assurances that we will not identify any potential or material control deficiencies before the end of our fiscal year, that we will be able to remediate in a timely manner any potential control deficiencies that may be identified, nor any assurances that any potential control deficiencies that may be identified will not rise to the level of significant deficiencies or material weaknesses. For more information, please see Risk Factors. We may be unable to comply with certain

requirements and deadlines of the Sarbanes-Oxley Act of 2002 relating to internal controls and procedures.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

In addition to the California state and federal investigations described in Business Government Regulation Certification and Licenses and Risk Factors Our operations and facilities are subject to stringent laws and regulations and if we are unable to comply, our business may be significantly harmed , we are involved in various legal proceedings arising in the ordinary course of business.

As previously reported, in May and June 2002, we were named as a defendant, together with certain of our current or former board members and officers, in four substantially identical class-action lawsuits filed in the United States District Court for the Central District of California, and subsequently consolidated as *In re Specialty Laboratories Securities Litigation* . The lawsuit purports to state claims on behalf of an alleged class of investors who bought our stock in the open market between December 8, 2000 and April 15, 2002 (Class Period). The lawsuit alleges that the market price of our stock was artificially inflated during the Class Period as a result of alleged misrepresentations made in violation of the Securities Act of 1933 and the Securities Exchange Act of 1934 in connection with our initial public offering of common stock and subsequent public disclosures. The lawsuit alleges, among other things, false and misleading statements about our compliance with certain regulatory requirements imposed by the California Department of Health Services and the federal Centers for Medicare & Medicaid Services. Plaintiffs seek compensatory damages, including interest, costs and expenses, attorneys' fees, and other relief. Plaintiffs have filed several amended complaints, and we in turn have filed motions to dismiss these complaints. The court ruled on these motions, dismissing some claims and not dismissing others, and allowed plaintiffs to proceed with their claims against the Company and several current and former officers and directors for alleged violations of both the Securities Act of 1933 and the Securities Exchange Act of 1934. We have provided notice to our directors and officer's insurers, and believe that we have insurance applicable to the defense of the lawsuits. We also believe that the claims against us and our current and former officers and directors are without merit, and intend to defend these lawsuits vigorously. On June 14, 2004, we announced an agreement in principle to settle the consolidated lawsuits for \$12 million, which is to be paid fully by our insurance carriers. On October 15, 2004, the court entered an order preliminarily approving the settlement and providing for notice to shareholders. As the settlement and defense costs are being paid by our insurance carriers, we do not anticipate any costs associated with the defense or settlement of the claims to have a material impact on our finances.

Also as previously reported, Specialty Laboratories Asia Pte. Ltd., a Singapore corporation, (SLA), is 60% owned by our wholly-owned subsidiary, Specialty Laboratories International Ltd., a British Virgin Islands corporation (SLIL). SLA was headquartered in Singapore but, in early 1999, SLA ceased all operations and is currently insolvent. A former employee of SLA has obtained a judgment for \$350,000 against SLA and a default judgment of approximately \$1.95 million in a wrongful termination action against SLA filed by him in Singapore. The former employee has filed an action against SLA in San Diego Superior Court to attempt to collect on the Singapore judgment and has obtained a default judgment of approximately \$2.5 million against SLA in California. The former employee served discovery upon us and certain of our directors and officers. Our management believes that any claim against us or our directors and officers in connection with these judgments, if made, would be without merit, and we would vigorously defend any such action.

In December 2003, we were served with an action in which we are named as a defendant, together with certain of our former officers, SLIL, and multiple other parties located in Singapore and India, in a lawsuit brought in the High Court of the Republic of Singapore by Dragon Investment Company (Dragon), one of the shareholders in SLA. Dragon has also brought the lawsuit in the name of SLA as a derivative action. The lawsuit alleges, among other things, that SLA and Dragon suffered

damages as a result of the winding up of the affairs of SLA and disposition of its assets. The lawsuit also alleges that certain of the defendants breached certain written agreements to allow Dragon to acquire more shares of SLA, that certain of our former officers conspired to run down and dissipate the assets of SLA, and that they fraudulently concealed their actions from Dragon and the other minority shareholder of SLA. We have provided notice to the applicable insurance carriers. While we believe that we have insurance applicable to the defense of the lawsuits, and continue to work with the relevant insurance carriers on the coverage issue, such carriers have not yet acknowledged coverage of the matter.

On June 14, 2004 we became aware of a lawsuit filed against us in the U.S. District Court for the Southern District of California by Prometheus Laboratories, Inc. (Prometheus). The complaint alleged infringement of Prometheus patent rights by a new assay we announced for the monitoring of drug levels in connection with the treatment of Inflammatory Bowel Disease. Based partly on the threat of the litigation, and the service disruption the lawsuit could have on our clients, we chose not to make this new assay available to our clients, and the matter with Prometheus was resolved without admission of liability or the payment of any settlement amounts. Prometheus has since dismissed their lawsuit against us.

From time to time, we receive letters alleging infringement of patent or other intellectual property rights. Our management believes that these letters generally are without merit and intend to contest them vigorously. For more information, please see Risk Factors Our assays may infringe on the intellectual property rights of others, which may cause us to engage in costly litigation and/or enter into appropriate licenses which may cause us to pay substantial damages or royalties, and could prohibit or restrict us from selling our assays.

ITEM 2. CHANGES IN SECURITIES AND USE OF PROCEEDS

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

None.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

(a) Exhibits.

The following exhibits are filed as part of, or are incorporated by reference in, this Quarterly Report.

- 3.1 Articles of Incorporation. (1)
- 3.2 Form of By-laws. (1)
- 4.1 Specimen Common Stock Certificate. (1)
- 4.2 See Exhibits 3.1 and 3.2 for provisions of the Articles of Incorporation and By-laws of the Registrant defining the rights of holders of Common Stock of the Registrant.
- 10.12000 Stock Incentive Plan. (1)
- 10.22000 Employee Stock Purchase Plan. (1)
- 10.3 Lease dated June 1996, as amended on October 24, 2002, between Howard Real Property Trust (Lessor) and Registrant (Lessee) for the property located at 1752-1756 Cloverfield, Santa Monica, California. (7)
- 10.4 Sublease dated July 9, 1996, as amended on March 9, 1998 between The Rand Corporation (Sublandlord) and Registrant (Subtenant) for the property located at 1620 20th Street, Santa Monica, California. (1) (Superceded by Exhibit 10.38)
- 10.5 Lease dated January 26, 2000, as amended on November 22, 2002, between WDI Santa Monica LLC (Lessor) and Registrant (Lessee) for the property located at 1756 22nd Street, Santa Monica, California. (7)
- 10.6 Lease dated July 17, 1993, as amended on October 24, 2002, between Oscar & Ethel Salenger Trust (Landlord) and Registrant (Tenant) for the property located at 2211 Michigan Avenue, Santa Monica, California. (7)
- +10.7 Agreement dated August 26, 1996, as amended on October 23, 1998 and as amended on December 31, 1999 between Triple G Corporation and Registrant. (1)
- +10.8 Expanded PCR Diagnostics Services Agreement dated August 20, 2001 by and between Roche Molecular Systems, Inc. and Registrant. (6)
- +10.9 Group Purchasing Agreement effective as of July 15, 1998 between AmeriNet, Inc. and Registrant as amended. (3)
- +10.10 Laboratory Services Agreement effective as of March 1, 1999 between Joint Purchasing Corporation and Registrant. (1)
- +10.11 Agreement dated June 7, 2000 between Managed Health Care Associates and Registrant. (1)
- +10.12 Shared Services Health Care letter of confirmation dated June 5, 2000. (1)
- 10.13 License Agreement, undated, between Southern California Edison Company (Licensor) and Registrant (Licensee) regarding Santa Monica Service Center property. (1)
- 10.14 Employment Agreement dated May 15, 2002 between Douglas S. Harrington and Registrant. (8)
- 10.15 James B. Peter, M.D., Ph.D. severance agreement dated June 7, 2002. (5)
- 10.16 Paul F. Beyer severance agreement dated June 6, 2002. (5)
- +10.17 Purchase and License Agreement dated June 19, 2000 between Sequenom, Inc. and Registrant. (1)
- +10.18 Letter Agreement dated April 14, 2000 between Third Wave Technologies, Inc. and Registrant. (1)

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- +10.19 Collaborative Research, Development and License Agreement dated May 9, 2000 between Epoch Biosciences, Inc. (formerly known as Epoch Pharmaceuticals, Inc.) and Registrant. (1)
- +10.20 License Agreement dated March 15, 2000 between Gen-Probe Incorporated and Registrant. (1)
- 10.21 Albert Rabinovitch, M.D., Ph.D. severance agreement dated June 10, 2002. (5)
- 10.22 Asset Purchase Agreement among Registrant, Boston Biomedica, Inc. and BBI Clinical Laboratories, Inc. (2)
- 10.23 Marketing Arrangement dated April 5, 2001 between Axis-Shield Diagnostics Limited and Registrant, as amended. (4)
- 10.24 Employment Agreement dated January 28, 2003 between Thomas E. England and Registrant. (8)
- 10.25 Employment Agreement dated September 11, 2003 between Frank J. Spina and Registrant. (9)
- 10.26 Employment Agreement dated September 11, 2003 between Dan R. Angress and Registrant. (9)
- 10.27 Employment Agreement dated September 11, 2003 between Mark R. Willig and Registrant. (9)
- 10.28 Employment Agreement dated September 11, 2003 between Michael C. Dugan, M.D. and Registrant. (9)
- 10.29 Employment Agreement dated September 11, 2003 between Thomas J. Kosco and Registrant. (9)
- 10.30 Employment Agreement dated September 11, 2003 between Robert M. Harman and Registrant. (9)
- 10.31 Employment Agreement dated September 11, 2003 between Nicholas R. Simmons and Registrant. (9)
- 10.32 Employment Agreement dated September 11, 2003 between Cheryl G. Gallarda and Registrant. (9)
- 10.33 Employment Agreement dated September 11, 2003 between Cynthia K. French and Registrant. (9)
- +10.34 Agreement dated August 15, 2003 between Bayer Healthcare, LLC and Registrant. (9)
- +10.35 Agreement dated August 15, 2003 between Chiron Corporation and Registrant. (9)
- 10.36 Agreement dated September 24, 2003 between CIT Group/Business Credit, Inc. and Registrant. (9)
- 10.37 Employment Agreement dated December 10, 2003 between Maryam Sadri and Registrant. (10)
- 10.38 Lease dated January 12, 2004 between Water Garden Company L.L.C. (Landlord) and Registrant (Tenant) for the property located at 1620 26th Street, Santa Monica, California. (10)
- 10.39 Agreement for Sale and Leaseback dated February 22, 2004 between Lexington Corporate Properties Trust (Buyer) and Registrant (Seller) for property located at 27027 Tourney Road, Santa Clarita, California. (11)
- 10.40 Construction Funding Agreement dated March 11, 2004 between Lexington Lion Clarita L.P. (Owner) and Registrant (Tenant) for property located at 27027 Tourney Road, Santa Clarita, California. (11)
- 10.41 Lease dated March 18, 2004 between Lexington Lion Clarita L.P. (Landlord) and Registrant (Tenant) for property located at 27027 Tourney Road, Santa Clarita, California. (11)
- 10.42 Separation Agreement dated March 14, 2004 between Frank J. Spina and Registrant. (11)
- 10.43 Employment Agreement dated April 12, 2004 between Kevin R. Sayer and Registrant. (11)
- 10.44 First Amendment to Lease dated June 2, 2004 between Water Garden Company, L.L.C. (Landlord) and Registrant (Tenant) for the property located at 1620 26th Street, Santa Monica, California. (12)
- *10.45 First amendment to credit agreement dated August 13, 2004 between CIT Group/Business Credit, Inc. and Registrant.
- ±*10.46 Agreement effective November 1, 2004 between Novation and Registrant.
- *31.1 Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) under the Securities Exchange Act of 1934.
- *31.2 Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) under the Securities Exchange Act of 1934.
- *32.1 Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002.
- 99.1 California Department of Health Services Letter dated June 28, 2002. (6)
- 99.2 Center for Medicare and Medicaid Services Letter dated July 17, 2002. (6)

99.3 California Department of Health Services Letter dated July 18, 2002. (6)

* Filed herewith.

Indicates a management contract or compensatory agreement.

+ Confidential treatment requested and received as to certain portions of this agreement.

± Confidential treatment requested as to certain portions of this agreement.

(1) This exhibit was previously filed as an exhibit to the Company's Registration Statement on Form S-1 declared effective on December 7, 2000 (File No. 333-45588) and is incorporated by reference herein.

(2) This exhibit was previously filed as an exhibit to the Company's Annual Report on Form 10-K for the period ended December 31, 2000 with the Securities & Exchange Commission on March 30, 2001 and is incorporated by reference herein.

(3) This exhibit was originally filed as an exhibit to the Company's Registration Statement on Form S-1 declared effective on December 7, 2000 and an amendment was filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the period ended June 30, 2001 on August 10, 2001 and is incorporated by reference herein.

(4) This exhibit was previously filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the period ended June 30, 2001 with the Securities & Exchange Commission on August 10, 2001 and is incorporated by reference herein.

(5) This exhibit was originally filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the period ending June 30, 2002 with the Securities and Exchange Commission on August 13, 2002 and is incorporated herein for reference.

(6) This exhibit was originally filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the period ending September 30, 2002 with the Securities and Exchange Commission on October 30, 2002 and is incorporated herein for reference.

(7) This exhibit was originally filed as an exhibit to the Company's Registration Statement on Form S-1 declared effective on December 7, 2000 and an amendment was filed as an exhibit to the Company's Annual Report on Form 10-K for the period ended December 31, 2002 on March 21, 2003 and is incorporated by reference herein.

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(8) This exhibit was originally filed as an exhibit to the Company's Annual Report on Form 10-K for the period ending December 31, 2002 with the Securities and Exchange Commission on March 21, 2003 and is incorporated herein for reference.

(9) This exhibit was originally filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the period ending September 30, 2003 with the Securities and Exchange Commission on November 14, 2003 and is incorporated herein for reference.

(10) This exhibit was originally filed as an exhibit to the Company's Annual Report on Form 10-K for the period ending December 31, 2003 with the Securities and Exchange Commission on March 15, 2004 and is incorporated herein for reference.

(11) This exhibit was originally filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the period ending March 31, 2004 with the Securities and Exchange Commission on May 12, 2004 and is incorporated herein for reference.

(12) This exhibit was originally filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the period ending June 30, 2004 with the Securities and Exchange Commission on August 9, 2004 and is incorporated herein for reference.

(b) Reports on Form 8-K:

On July 21, 2004, the Company filed a report on Form 8-K (Items 7, 9 and 12) with respect to its results of operations for the quarter ended June 30, 2004, attaching a copy of a press release containing financial results for such periods.

On September 20, 2004, the Company filed a report on Form 8-K (Items 5, 7 and 9) to report that Mr. Thomas R. Testman resigned from its Board of Directors effective September 15, 2004 and that Mr. Richard K. Whitney had been appointed to its Board of Directors effective September 16, 2004 to fill the vacancy resulting from Mr. Testman's resignation, attaching a related press release.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this Quarterly Report on Form 10-Q to be signed on its behalf by the undersigned, thereunto duly authorized.

SPECIALTY LABORATORIES, INC.,
a California corporation

Dated: November 9, 2004 By: /s/ Douglas S. Harrington
 Name: Douglas S. Harrington
 Title: *Chief Executive Officer and Director*

Dated: November 9, 2004 By: /s/ Kevin R. Sayer
 Name: Kevin R. Sayer
 Title: *Chief Financial Officer (Principal Financial and Accounting Officer)*

EXHIBIT INDEX

- 3.1 Articles of Incorporation. (1)
- 3.2 Form of By-laws. (1)
- 4.1 Specimen Common Stock Certificate. (1)
- 4.2 See Exhibits 3.1 and 3.2 for provisions of the Articles of Incorporation and By-laws of the Registrant defining the rights of holders of Common Stock of the Registrant.
- 10.12000 Stock Incentive Plan. (1)
- 10.22000 Employee Stock Purchase Plan. (1)
- 10.3 Lease dated June 1996, as amended on October 24, 2002, between Howard Real Property Trust (Lessor) and Registrant (Lessee) for the property located at 1752-1756 Cloverfield, Santa Monica, California. (7)
- 10.4 Sublease dated July 9, 1996, as amended on March 9, 1998 between The Rand Corporation (Sublandlord) and Registrant (Subtenant) for the property located at 1620 20th Street, Santa Monica, California. (1) (Superceded by Exhibit 10.38)
- 10.5 Lease dated January 26, 2000, as amended on November 22, 2002, between WDI Santa Monica LLC (Lessor) and Registrant (Lessee) for the property located at 1756 22nd Street, Santa Monica, California. (7)
- 10.6 Lease dated July 17, 1993, as amended on October 24, 2002, between Oscar & Ethel Salenger Trust (Landlord) and Registrant (Tenant) for the property located at 2211 Michigan Avenue, Santa Monica, California. (7)
- +10.7 Agreement dated August 26, 1996, as amended on October 23, 1998 and as amended on December 31, 1999 between Triple G Corporation and Registrant. (1)
- +10.8 Expanded PCR Diagnostics Services Agreement dated August 20, 2001 by and between Roche Molecular Systems, Inc. and Registrant. (6)
- +10.9 Group Purchasing Agreement effective as of July 15, 1998 between AmeriNet, Inc. and Registrant as amended. (3)
- +10.10 Laboratory Services Agreement effective as of March 1, 1999 between Joint Purchasing Corporation and Registrant. (1)
- +10.11 Agreement dated June 7, 2000 between Managed Health Care Associates and Registrant. (1)
- +10.12 Shared Services Health Care letter of confirmation dated June 5, 2000. (1)
- 10.13 License Agreement, undated, between Southern California Edison Company (Licensor) and Registrant (Licensee) regarding Santa Monica Service Center property. (1)
- 10.14 Employment Agreement dated May 15, 2002 between Douglas S. Harrington and Registrant. (8)
- 10.15 James B. Peter, M.D., Ph.D. severance agreement dated June 7, 2002. (5)
- 10.16 Paul F. Beyer severance agreement dated June 6, 2002. (5)
- +10.17 Purchase and License Agreement dated June 19, 2000 between Sequenom, Inc. and Registrant. (1)
- +10.18 Letter Agreement dated April 14, 2000 between Third Wave Technologies, Inc. and Registrant. (1)
- +10.19 Collaborative Research, Development and License Agreement dated May 9, 2000 between Epoch Biosciences, Inc. (formerly known as Epoch Pharmaceuticals, Inc.) and Registrant. (1)
- +10.20 License Agreement dated March 15, 2000 between Gen-Probe Incorporated and Registrant. (1)
- 10.21 Albert Rabinovitch, M.D., Ph.D. severance agreement dated June 10, 2002. (5)
- 10.22 Asset Purchase Agreement among Registrant, Boston Biomedica, Inc. and BBI Clinical Laboratories, Inc. (2)
- 10.23 Marketing Arrangement dated April 5, 2001 between Axis-Shield Diagnostics Limited and Registrant, as amended. (4)
- 10.24 Employment Agreement dated January 28, 2003 between Thomas E. England and Registrant. (8)
- 10.25 Employment Agreement dated September 11, 2003 between Frank J. Spina and Registrant. (9)
- 10.26 Employment Agreement dated September 11, 2003 between Dan R. Angress and Registrant. (9)
- 10.27 Employment Agreement dated September 11, 2003 between Mark R. Willig and Registrant. (9)
- 10.28 Employment Agreement dated September 11, 2003 between Michael C. Dugan, M.D. and Registrant. (9)

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- 10.29 Employment Agreement dated September 11, 2003 between Thomas J. Kosco and Registrant. (9)
- 10.30 Employment Agreement dated September 11, 2003 between Robert M. Harman and Registrant. (9)
- 10.31 Employment Agreement dated September 11, 2003 between Nicholas R. Simmons and Registrant. (9)
- 10.32 Employment Agreement dated September 11, 2003 between Cheryl G. Gallarda and Registrant. (9)
- 10.33 Employment Agreement dated September 11, 2003 between Cynthia K. French and Registrant. (9)
- +10.34 Agreement dated August 15, 2003 between Bayer Healthcare, LLC and Registrant. (9)
- +10.35 Agreement dated August 15, 2003 between Chiron Corporation and Registrant. (9)
- 10.36 Agreement dated September 24, 2003 between CIT Group/Business Credit, Inc. and Registrant. (9)
- 10.37 Employment Agreement dated December 10, 2003 between Maryam Sadri and Registrant. (10)
- 10.38 Lease dated January 12, 2004 between Water Garden Company L.L.C. (Landlord) and Registrant (Tenant) for the property located at 1620 26th Street, Santa Monica, California. (10)
- 10.39 Agreement for Sale and Leaseback dated February 22, 2004 between Lexington Corporate Properties Trust (Buyer) and Registrant (Seller) for property located at 27027 Tourney Road, Santa Clarita, California. (11)
- 10.40 Construction Funding Agreement dated March 11, 2004 between Lexington Lion Clarita L.P. (Owner) and Registrant (Tenant) for property located at 27027 Tourney Road, Santa Clarita, California. (11)
- 10.41 Lease dated March 18, 2004 between Lexington Lion Clarita L.P. (Landlord) and Registrant (Tenant) for property located at 27027 Tourney Road, Santa Clarita, California. (11)
- 10.42 Separation Agreement dated March 14, 2004 between Frank J. Spina and Registrant. (11)
- 10.43 Employment Agreement dated April 12, 2004 between Kevin R. Sayer and Registrant. (11)
- 10.44 First Amendment to Lease dated June 2, 2004 between Water Garden Company, L.L.C. (Landlord) and Registrant (Tenant) for the property located at 1620 26th Street, Santa Monica, California. (12)
- *10.45 First amendment to credit agreement dated August 13, 2004 between CIT Group/Business Credit, Inc. and Registrant.
- ±*10.46 Agreement effective November 1, 2004 between Novation and Registrant.
- *31.1 Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) under the Securities Exchange Act of 1934.
- *31.2 Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) under the Securities Exchange Act of 1934.
- *32.1 Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002.
- 99.1 California Department of Health Services Letter dated June 28, 2002. (6)
- 99.2 Center for Medicare and Medicaid Services Letter dated July 17, 2002. (6)
- 99.3 California Department of Health Services Letter dated July 18, 2002. (6)

* Filed herewith.

Indicates a management contract or compensatory agreement.

+ Confidential treatment requested and received as to certain portions of this agreement.

± Confidential treatment requested as to certain portions of this agreement.

(1) This exhibit was previously filed as an exhibit to the Company's Registration Statement on Form S-1 declared effective on December 7, 2000 (File No. 333-45588) and is incorporated by reference herein.

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(2) This exhibit was previously filed as an exhibit to the Company's Annual Report on Form 10-K for the period ended December 31, 2000 with the Securities & Exchange Commission on March 30, 2001 and is incorporated by reference herein.

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- (3) This exhibit was originally filed as an exhibit to the Company's Registration Statement on Form S-1 declared effective on December 7, 2000 and an amendment was filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the period ended June 30, 2001 on August 10, 2001 and is incorporated by reference herein.
- (4) This exhibit was previously filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the period ended June 30, 2001 with the Securities & Exchange Commission on August 10, 2001 and is incorporated by reference herein.
- (5) This exhibit was originally filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the period ending June 30, 2002 with the Securities and Exchange Commission on August 13, 2002 and is incorporated herein for reference.
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- (12) This exhibit was originally filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the period ending June 30, 2004 with the Securities and Exchange Commission on August 9, 2004 and is incorporated herein for reference.

